

<b>Non-Quantitative Treatment Limitation (NQTL) Analysis Index</b>	
<b>Non-Quantitative Treatment Limitation</b>	Concurrent Review
<b>Plan Type(s) Applicable</b>	Cigna + Oscar
<b>Responsible Business Teams</b>	Clinical
<b>Names of Person(s) Responsible for Analysis Formation</b>	Insiya Taj, MPH, Associate, UM Optimization, (Over 3 years experience in healthcare and clinical research) Marco Fossati-Bellani, MD, MPH, Senior Medical Director, UM
<b>Last Update</b>	7/1/2022
<b>Reviewers</b>	Alexandra Rubino, Associate Director, MHP (Over 4 years experience in Mental Health Parity reporting and operational compliance)



## Non-Quantitative Treatment Limitation (NQTL) Analysis for the Mental Health Parity and Addiction Equity Act (MHPAEA)

### Concurrent Review

1. Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply:

Medical/Surgical Terms	Mental Health/Substance Use Disorder Terms
<b>Definition:</b> Concurrent review is a review of services when the member is actively receiving services or review for an extension of a previously approved number of treatments or ongoing course of treatment over a period of time.	<b>Definition:</b> Concurrent review is a review of services when the member is actively receiving services or review for an extension of a previously approved number of treatments or ongoing course of treatment over a period of time.

Benefit Classification	Medical/Surgical Services to which the NQTL applies	Mental Health/SUD Services to which the NQTL applies
In-Network/Out-of-Network Inpatient Services	<p>All inpatient services are subject to this NQTL.</p> <ul style="list-style-type: none"> <li>• Acute/Elective Hospital</li> <li>• Hospice</li> <li>• Long-Term Acute Care</li> <li>• Rehabilitation, Acute/Subacute</li> <li>• Skilled Nursing Facility</li> </ul> <p>All non-emergent medical/surgical inpatient services reimbursed on a per diem basis are subject to concurrent care medical necessity review.</p> <p>Note: In-network medical/surgical inpatient services reimbursed on a DRG or case rate basis authorized upon pre service review are not</p>	<p>All inpatient services are subject to this NQTL.</p> <ul style="list-style-type: none"> <li>• All Inpatient Admissions (Non-emergent) <ul style="list-style-type: none"> <li>○ Acute hospital</li> <li>○ Rehabilitation, Acute/Subacute</li> <li>○ Residential treatment</li> </ul> </li> </ul> <p>All non-emergent MH/SUD inpatient services reimbursed on a per diem basis are subject to concurrent care medical necessity review.</p>

	subject to concurrent care review.	
In-Network/Out-of-Network Outpatient Services	<ul style="list-style-type: none"> <li>• Physician-Administered Drugs</li> <li>• Certain DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) such as oxygen, CPAP, and diabetic supplies</li> <li>• Home Health Care Services</li> <li>• Advanced Imaging</li> <li>• Diagnostic Tests &amp; Evaluations, Laboratory Procedures</li> <li>• Outpatient Treatments/Procedures</li> <li>• Non-Emergency Transportation</li> <li>• Unlisted Procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Adaptive Behavior Assessment &amp; Therapy</li> <li>• Applied behavior analysis (ABA)</li> <li>• Detoxification programs</li> <li>• Outpatient psychiatric testing</li> <li>• Partial hospitalization treatment</li> <li>• Transcranial magnetic stimulation (TMS)</li> </ul>

**2. Identify the factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits:**

<b>Benefit Classification</b>	<b>Factors Considered: Medical/Surgical</b>	<b>Factors Considered: Mental Health/SUD</b>
In-Network/ Out-of-Network Inpatient Services	<ol style="list-style-type: none"> <li>1. Clinical appropriateness</li> <li>2. Safety risk</li> <li>3. Cost</li> </ol>	<ol style="list-style-type: none"> <li>1. Clinical appropriateness</li> <li>2. Safety risk</li> <li>3. Cost</li> </ol>

In-Network/ Out-of-Network Outpatient Services	<ol style="list-style-type: none"> <li>1. Cost variability</li> <li>2. Denial rate</li> <li>3. Cost percentile</li> <li>4. Safety risk</li> <li>5. New/emerging service/technology</li> <li>6. Clinical appropriateness</li> </ol>	<ol style="list-style-type: none"> <li>1. Cost variability</li> <li>2. Denial rate</li> <li>3. Cost percentile</li> <li>4. Safety risk</li> <li>5. New/emerging service/technology</li> <li>6. Clinical appropriateness</li> </ol>
--	--	--

**3. Identify the evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Evidentiary Standards and Sources: Medical/Surgical	Evidentiary Standards and Sources: MH/SUD
In-Network/ Out-of-Network Inpatient Services	<ol style="list-style-type: none"> <li>1. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</li> </ol> <p>Examples:</p>	<ol style="list-style-type: none"> <li>1. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</li> </ol> <p>Examples:</p>

	<ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> </ul>	<ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> </ul>
--	--	--

	<ul style="list-style-type: none"> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul> <p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p> <p>2. <b>Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health</p>	<ul style="list-style-type: none"> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul> <p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p> <p>2. <b>Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health</p>
--	--	--

	<p>agencies, Clinical criteria<sup>1</sup>, Clinical evidence<sup>2</sup></p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety:</i></p>	<p>agencies, Clinical criteria<sup>3</sup>, Clinical evidence<sup>4</sup></p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety:</i></p>
--	--	--

<sup>1</sup> Clinical criteria includes: Plan Clinical Guidelines, MCG, ASAM (SUD only), Hayes, UpToDate, National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)

<sup>2</sup> Clinical evidence: The US National Library of Medicine; Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN); Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH); Published scientific evidence; In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).

<sup>3</sup> Clinical criteria includes: Plan Clinical Guidelines, MCG, ASAM (SUD only), Hayes, UpToDate, National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)

<sup>4</sup> Clinical evidence: The US National Library of Medicine; Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN); Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH); Published scientific evidence; In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).

	<p><i>strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017</i>  (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</p> <p><b>3. High Cost</b></p> <p>Evidentiary Standard: The mean cost of an inpatient episode of care is &gt;\$12,000</p> <p>Source: Claims data</p>	<p><i>strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017</i>  (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</p> <p><b>3. High Cost</b></p> <p>Evidentiary Standard: The mean cost of an inpatient episode of care is &gt;\$12,000</p> <p>Source: Claims data</p>
In-Network/ Out-of-Network Outpatient Services	<p><b>1. Cost variability</b> is defined as the cost per episode of service (service units X unit cost) that trigger 2x the mean of other outpatient services and provided to a minimum of twenty unique Plan members. Outpatient services are subject to variability in cost per episode of service relative to other services within the classification of benefits. For each service, the Plan calculates the Average Annual Allowed Amount per Unique Patient with Outpatient Claim Events for that Primary Service.</p> <p>Source: Claims data</p> <p>Threshold: Cost per episode of service that triggers 2x the mean of other outpatient services.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Musculoskeletal Surgery   Joint arthroscopy / arthroplasty / arthrodesis</li> </ul>	<p><b>1. Cost variability</b> is defined as the cost per episode of service (service units X unit cost) that trigger 2x the mean of other outpatient services and provided to a minimum of twenty unique Plan members. Outpatient services are subject to variability in cost per episode of service relative to other services within the classification of benefits. For each service, the Plan calculates the Average Annual Allowed Amount per Unique Patient with Outpatient Claim Events for that Primary Service.</p> <p>Source: Claims data</p> <p>Threshold: Cost per episode of service that triggers 2x the mean of other outpatient services.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Musculoskeletal Surgery   Joint arthroscopy / arthroplasty / arthrodesis</li> </ul>

	<p>Cost variability applies to this service category. Cost variability is 5x the mean of other outpatient services.</p> <ul style="list-style-type: none"> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient Psychiatric Testing Cost variability applies to this service category. Cost variability is 2.9x the mean of other outpatient services.</li> </ul> <p><b>2. Denial rate</b> is defined as the percentage of prior authorization requests that are denied by the Plan.</p> <p>Source: Authorization data</p> <p>Threshold: &gt;10%</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Skin Treatments &amp; Procedures   UV / Laser therapy Denial rate applies to this service category. Denial rate is 70% for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Partial Hospitalization Denial rate applies to this service category. Denial rate is 60% for this service category.</li> </ul> <p><b>3. Cost percentile</b> is defined as the average cost per claim event for a particular outpatient service relative to other services within the classification of benefits.</p> <p>Source: Claims data</p>	<p>Cost variability applies to this service category. Cost variability is 5x the mean of other outpatient services.</p> <ul style="list-style-type: none"> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient Psychiatric Testing Cost variability applies to this service category. Cost variability is 2.9x the mean of other outpatient services.</li> </ul> <p><b>2. Denial rate</b> is defined as the percentage of prior authorization requests that are denied by the Plan.</p> <p>Source: Authorization data</p> <p>Threshold: &gt;10%</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Skin Treatments &amp; Procedures   UV / Laser therapy Denial rate applies to this service category. Denial rate is 70% for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Partial Hospitalization Denial rate applies to this service category. Denial rate is 60% for this service category.</li> </ul> <p><b>3. Cost percentile</b> is defined as the average cost per claim event for a particular outpatient service relative to other services within the classification of benefits.</p> <p>Source: Claims data</p>
--	--	--

	<p>Threshold: ≥ 85th Percentile</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Digestive Treatments &amp; Procedures   Bariatric surgery Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> <li>• Benefit: Mental Health/Substance Use Disorder Service: Outpatient psychiatric testing Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> </ul> <p><b>4. Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health agencies, Clinical criteria, Clinical evidence</p> <ul style="list-style-type: none"> <li>• Centers for Medicare &amp; Medicaid Services</li> <li>• World Health Organization</li> <li>• Institute For Safe Medication Practices</li> <li>• U.S. Food and Drug Administration</li> </ul>	<p>Threshold: ≥ 85th Percentile</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Digestive Treatments &amp; Procedures   Bariatric surgery Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> <li>• Benefit: Mental Health/Substance Use Disorder Service: Outpatient psychiatric testing Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> </ul> <p><b>4. Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health agencies, Clinical criteria, Clinical evidence</p> <ul style="list-style-type: none"> <li>• Centers for Medicare &amp; Medicaid Services</li> <li>• World Health Organization</li> <li>• Institute For Safe Medication Practices</li> <li>• U.S. Food and Drug Administration</li> </ul>
--	--	--

	<ul style="list-style-type: none"> <li>● Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>● Treatments that increase the likelihood of adverse health effects</li> <li>● Services that increase the likelihood of perioperative morbidity and mortality</li> <li>● Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>● Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>● Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017</i> (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>● The US National Library of Medicine;</li> <li>● Guidelines and publications from</li> </ul>	<ul style="list-style-type: none"> <li>● Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>● Treatments that increase the likelihood of adverse health effects</li> <li>● Services that increase the likelihood of perioperative morbidity and mortality</li> <li>● Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>● Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>● Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017</i> (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>● The US National Library of Medicine;</li> <li>● Guidelines and publications from</li> </ul>
--	--	--

	<p>professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</p> <ul style="list-style-type: none"> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Surgical procedures at risk for infection and complications (e.g., gastrectomy, hip replacement)</li> <li>• Advanced radiology procedures with exposure to radiation (e.g., CT, MRI, nuclear medicine)</li> <li>• Physician-administered drugs due to the risk for adverse effects and contraindications (e.g., chemotherapeutic agents)</li> </ul> <p><b>5. New/ Emerging Service/ Technology</b> is defined as any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven. Services that are not accepted as the standard medical treatment of the condition being treated are considered “new and emerging services and technologies.” This includes any health care service, testing, procedure, treatment, device, or prescription drug that:</p> <ul style="list-style-type: none"> <li>• Is not accepted as</li> </ul>	<p>professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</p> <ul style="list-style-type: none"> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Surgical procedures at risk for infection and complications (e.g., gastrectomy, hip replacement)</li> <li>• Advanced radiology procedures with exposure to radiation (e.g., CT, MRI, nuclear medicine)</li> <li>• Physician-administered drugs due to the risk for adverse effects and contraindications (e.g., chemotherapeutic agents)</li> </ul> <p><b>5. New/ Emerging Service/ Technology</b> is defined as any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven. Services that are not accepted as the standard medical treatment of the condition being treated are considered “new and emerging services and technologies.” This includes any health care service, testing, procedure, treatment, device, or prescription drug that:</p> <ul style="list-style-type: none"> <li>• Is not accepted as</li> </ul>
--	--	--

	<p>standard medical treatment of the condition; or</p> <ul style="list-style-type: none"> <li>• Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; or</li> <li>• Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or</li> <li>• Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; or</li> <li>• Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g.,</li> </ul>	<p>standard medical treatment of the condition; or</p> <ul style="list-style-type: none"> <li>• Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; or</li> <li>• Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or</li> <li>• Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; or</li> <li>• Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g.,</li> </ul>
--	--	--

	ACOG, APA, NCCN, WPATH)	ACOG, APA, NCCN, WPATH)
	<p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Genetic, biomarker and molecular tests</li> <li>• Medical devices and implants</li> <li>• Novel therapies (e.g., gene therapy, CAR T-Cell therapy)</li> </ul> <p>6. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as</p>	<p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Genetic, biomarker and molecular tests</li> <li>• Medical devices and implants</li> <li>• Novel therapies (e.g., gene therapy, CAR T-Cell therapy)</li> </ul> <p>6. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as</p>

	<p>treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul>	<p>treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul>
--	--	--

	<p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul>	<p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul>
	<p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p>	<p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p>

**4. Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the**



processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and

*For each MH/SUD benefit subject to Concurrent Review, identify which of the factor(s) in Step 3 were met:*

#### **In-Network/Out-of-Network Outpatient M/S**

<b>Service</b>	<b>Cost variability</b>	<b>Denial rate</b>	<b>Cost percentile</b>	<b>Safety risk</b>	<b>New/ Emerging Service/ Technology</b>	<b>Clinical Appropriateness</b>
Physician-Administered Drugs		<b>X</b>		<b>X</b>	<b>X</b>	<b>X</b>
DMEPOS		<b>X</b>	<b>X</b>		<b>X</b>	<b>X</b>
Home Health Care Services		<b>X</b>				<b>X</b>
Advanced Imaging		<b>X</b>		<b>X</b>		
Diagnostic Tests & Evaluations, Laboratory Procedures		<b>X</b>	<b>X</b>		<b>X</b>	<b>X</b>
Treatments/Procedures	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Non-Emergency Transportation		<b>X</b>	<b>X</b>			
Unlisted Procedures	<b>X</b>	<b>X</b>		<b>X</b>	<b>X</b>	

#### **In-Network/Out-of-Network Outpatient MH/SUD**

Service	Cost variability	Denial rate	Cost percentile	Safety risk	New/ Emerging Service/ Technology	Clinical Appropriateness
Adaptive Behavior Assessment & Therapy	X					X
Applied behavior analysis (ABA)	X					X
Detoxification programs	X		X			
Outpatient psychiatric testing	X	X	X			
Partial hospitalization treatment	X	X				X
Transcranial magnetic stimulation (TMS)	X					X

Concurrent Review Process M/S	Concurrent Review Process MH/SUD
<p><b>Description:</b> Concurrent review is a review of services when the member is actively receiving services or review for an extension of a previously approved number of treatments or ongoing course of treatment over a period of time.</p> <p><b>Application of Concurrent Review:</b> A concurrent review is conducted when the Plan receives a request for coverage for medical care or services made while the member is in the process of receiving the requested medical care or services.</p>	

**Concurrent Review Submissions:** Concurrent review requests are submitted via fax, phone, or electronically via the Plan's provider portal.

**Concurrent Review Process:** During concurrent reviews, only the necessary and relevant sections of medical records are requested, i.e., those needed to verify medical necessity. In cases where the Plan does not receive the specific information requested, or if the information is not complete by the timeframe in which a notification of determination must be made, a determination will be made based upon the information available at that time. All reviews are conducted by licensed clinicians; the clinicians assess if the services being requested meet medical necessity based on established clinical criteria.

**Guidelines/Criteria used:** Clinicians make determinations based on plan benefits and established evidence-based clinical criteria.

**Staff qualifications:** Concurrent reviews are conducted by licensed clinicians; only board certified physicians make adverse determinations.

**Notification of Determination:** A written notification is issued to the member and provider within state, federal, or accreditation required timeframes; the written notification includes information on appeal rights.

**Timeframe for the Plan to respond:** The Plan follows all state, federal, and accreditation timeframe requirements.

**Peer to Peer:** After an adverse determination has been issued, the Plan offers the opportunity for the provider to discuss the request with a Plan physician. This peer to peer discussion is not considered part of a grievance or appeal process.

The Plan requires the requesting provider to submit the following information when requesting an authorization:

- Member information (name, Plan ID, date of birth).
- Facility (if applicable).
- Referring and treating provider name, National Provider Identifier (NPI), and Taxpayer Identification Number (TIN).
- Treatment information including diagnostic and/or procedure codes, requested amount and length of treatment(s).

Both the providers and members are notified of the determination consistent with state, federal and accreditation requirements and applicable appeal rights are provided.



*For each committee used to determine which benefits to subject to Concurrent Review, describe the committee's purpose, composition and member qualifications, and process:*

Committee Information M/S	Committee Information MH/SUD
<p>The OMC Board of Directors has the ultimate authority and responsibility for the quality of care and services delivered to its members. The Board of Directors provides strategic planning and direction, budget approval, and staff allocation for the UM Department. The Board of Directors assigns day-to-day responsibility for implementation of the UM Program to the UM Subcommittee, which is a subcommittee of the Quality Improvement Committee. The Board of Directors oversees the implementation of and adherence to the UM Program through the UM Subcommittee. The UM Subcommittee reports to the Quality Improvement Committee at a minimum of once per quarter, per year. The UM Program and Annual Program Evaluation are approved at the UM Subcommittee portion of the Quality Improvement Committee meeting. Minutes conveying this approval are submitted to the Board of Directors, who approve the actions of the Quality Improvement Committee. The Board of Directors delegates the responsibility for the oversight and operations of the UM Program to the Chief Medical Director (CMO). The CMO oversees the UM Program with input from the Quality Improvement Committee, and support from members of the UM staff (clinical and non-clinical).</p> <p>As noted above, the UM Subcommittee is a sub-committee to the Quality Improvement Committee. A senior-level physician chairs the UM Subcommittee with representation from licensed physicians (MD, DO) and licensed nurses (RN). Key health plan functions are represented at the meeting, including participation of the behavioral health designated physician (MD, clinical PhD, PsyD). Additional internal department representatives attend based on identified needs. The UM Subcommittee meets quarterly, or more frequently as necessary.</p> <p>The UM Subcommittee undertakes, but is not limited to, the following ongoing activities:</p> <ul style="list-style-type: none"> <li>• Evaluates and refines the UM Program through analysis of curated objective metrics and subjective feedback from members and Providers, making recommendations for intervention when indicated.</li> <li>• Reviews and approves modifications to the UM Program as indicated by operational needs and/or to meet regulatory and accreditation compliance.</li> <li>• Reviews and approves written Clinical Criteria and protocols for the determination of medical necessity and appropriateness of healthcare procedures and services.</li> <li>• Reviews and approves modifications to the healthcare procedures and services subject to Prior Authorization.</li> </ul>	

*Identify and define the factors and processes that are used to monitor and evaluate the application of Concurrent Review:*

Benefit Classification	Process Description: Medical/Surgical	Process Description: MH/SUD
In-Network Inpatient	The Plan ensures that processes, strategies, and evidentiary standards used in applying concurrent review is comparable and no more stringently applied to mental	

## Services/Outpatient Services

health/substance use disorder (MH/SUD) and medical/surgical (M/S) benefits, both as written and in operation. This includes the concurrent review request process, governance of the concurrent review list, and factors, sources, and evidentiary standards that contribute to the development of the concurrent review list.

The factors, sources, evidentiary standards, and process for concurrent review decisions are the same across M/S benefits and MH/SUD benefits. For both M/S and MH/SUD benefits, medical necessity review is conducted by licensed clinicians, and medical necessity determinations are based on whether the treatment/services are consistent with the member's coverage, medically appropriate, and consistent with evidence-based practice. Concurrent Review processes for M/S benefits and MH/SUD benefits follow state, federal, or accreditation timeframe requirements. Therefore, as-written, concurrent review is applied no more stringently to MH/SUD benefits when compared to M/S benefits.

Operationally, the Plan performs in-operation data assessments to ensure that factors, sources, and evidentiary standards are applied in a consistent manner. For UM, the Plan reviews rates of denials for concurrent review across benefit categories and compares these denial rates for M/S services against MH/SUD services. While data outcomes are not determinative of mental health parity compliance, the Plan uses these denial results to guide if investigations into UM processes are necessary to ensure that underlying methodology for UM procedures are applied no more stringently toward behavioral health services.

### Findings:

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of In-Network Inpatient Concurrent Care Reviews Requests	26		394	
Total Number of In-Network Inpatient Concurrent Care Denials	0	0%	55	14%
Total Number of In-Network Inpatient Concurrent Care Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network Inpatient Concurrent Care Requests Denied as Not Medically Necessary	0	0%	55	14%

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of Out-of-Network Inpatient Concurrent Care Reviews Requests	11		29	
Total Number of Out-of-Network Inpatient Concurrent Care Denials	2	18%	6	21%
Total Number of Out-of-Network Inpatient Concurrent Care Requests Administratively Denied	0	0%	0	0%
Total Number of Out-of-Network Inpatient Concurrent Care Requests Denied as Not Medically Necessary	2	18%	6	21%

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of In-Network All Other Outpatient Concurrent Care Reviews Requests	18		30	
Total Number of In-Network All Other Outpatient Concurrent Care Denials	0	0%	6	20%
Total Number of In-Network All Other Outpatient Concurrent Care Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network All Other Outpatient Concurrent Care Requests Denied as Not Medically	0	0%	6	20%

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of In-Network Outpatient Office Visit Concurrent Care Reviews Requests	1		21	
Total Number of In-Network Outpatient Office Visit Concurrent Care Denials	0	0%	6	29%
Total Number of In-Network Outpatient Office Visit Concurrent Care Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network Outpatient Office Visit Concurrent Care Requests Denied as Not Medically	0	0%	6	29%
Total Number of In-Network Outpatient Office Visit Concurrent Authorization Requests Denied as EIU	0	0%	0	0%

I. Utilization Reviews Requests and Denied:		MH/SUD	MH/SUD Denial Rate	Med-Surg. (M/S)	M/S Denial Rate
Total Number of Out-of-Network All Other Outpatient Concurrent Care Reviews Requests	17			1	
Total Number of Out-of-Network All Other Outpatient Concurrent Care Denials	0		0%	0	0%
Total Number of Out-of-Network All Other Outpatient Concurrent Care Requests Administratively Denied	0		0%	0	0%
Total Number of Out-of-Network All Other Outpatient Concurrent Care Requests Denied as Not Medically	0		0%	0	0%

  

I. Utilization Reviews Requests and Denied:		MH/SUD	MH/SUD Denial Rate	Med-Surg. (M/S)	M/S Denial Rate
Total Number of Out-of-Network Outpatient Office Visit Concurrent Care Reviews Requests	0			4	
Total Number of Out-of-Network Outpatient Office Visit Concurrent Care Denials	0		#DIV/0!	0	0%
Total Number of Out-of-Network Outpatient Office Visit Concurrent Care Requests Administratively Denied	0		#DIV/0!	0	0%
Total Number of Out-of-Network Outpatient Office Visit Concurrent Care Requests Denied as Not Medically	0		#DIV/0!	0	0%

**5. Provide the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.**

In-Network and Out-of-Network Inpatient Services/Outpatient Services	<p>The underlying processes, strategies, evidentiary standards and other factors used to apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA for the following reasons:</p> <ol style="list-style-type: none"> <li>1. The factors, sources, and evidentiary standards used to determine the methodology for assigning services to the concurrent review list is the same for MH/SUD benefits and M/S services.</li> <li>2. As written, the same process is employed when rendering concurrent review decisions and for assigning services to the concurrent review list across MH/SUD benefits and M/S services.</li> <li>3. In-operation, the Plan performs in-operation data assessments to ensure that the underlying methodology for developing the concurrent review list is applied no more stringently to MH/SUD services when compared to M/S services. Across all categories of concurrent review requests in PY 2021, there are higher denial rates for concurrent review for M/S benefits when compared to MH/SUD benefits. The outcome measures show that concurrent review methodologies are comparable (or in this case the outcome measures are more favorable to MH/SUD benefits) because the metrics reveal more favorable outcomes for MH/SUD benefits with higher rates of approval for services overall.</li> </ol> <p><b>Findings/Conclusion:</b> The findings of the comparative analysis reveal that the process and methodology to apply concurrent review to MH/SUD benefits is comparable to, and applied no more stringently than, the process and methodology used to apply concurrent review to M/S benefits..</p>
--	--



<b>Non-Quantitative Treatment Limitation (NQTL) Analysis Index</b>	
<b>Non-Quantitative Treatment Limitation</b>	Experimental/Investigational Determinations
<b>Plan Type(s) Applicable</b>	Cigna + Oscar
<b>Responsible Business Teams</b>	Clinical
<b>Names of Person(s) Responsible for Analysis Formation</b>	Insiya Taj, MPH, Associate, UM Optimization, (Over 3 years experience in healthcare and clinical research) Marco Fossati-Bellani, MD, MPH, Senior Medical Director, UM Mimi Shim, MPH, RN, Associate Clinical Manager, Clinical Policy
<b>Last Update</b>	7/1/2022
<b>Reviewers</b>	Alexandra Rubino, Associate Director, MHP (Over 4 years experience in Mental Health Parity reporting and operational compliance)



## Non-Quantitative Treatment Limitation (NQTL) Analysis for the Mental Health Parity and Addiction Equity Act (MHPAEA)

### Experimental/Investigational Determinations

1. The specific plan or coverage terms or other relevant terms regarding Experimental/Investigational Determinations and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Medical/Surgical Terms	Mental Health/Substance Use Disorder Terms
<p><b>Definition:</b> A service is considered experimental or investigational when its safety and efficacy has not been established. They may have outcomes that are inferior to standard medical treatment, for which long-term clinical utility has been established.</p> <p>Medical/surgical services determined to be experimental, investigational and unproven are excluded from coverage.</p> <p>Experimental, investigational and unproven services are medical, surgical, diagnostic, or other health care technologies, supplies, treatments, procedures, drug therapies or devices that are determined by the Clinical Advisory Subcommittee to be:</p> <ul style="list-style-type: none"> <li>not demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;</li> <li>not approved by the U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency to be lawfully marketed for the proposed use;</li> <li>the subject of review or approval by an Institutional Review Board for the proposed use except as provided in the “Clinical Trials” section(s) of this plan; or</li> </ul>	<p><b>Definition:</b> A service is considered experimental or investigational when its safety and efficacy has not been established. They may have outcomes that are inferior to standard medical treatment, for which long-term clinical utility has been established.</p> <p>MH/SUD services determined to be experimental, investigational and unproven are excluded from coverage.</p> <p>Experimental, investigational and unproven services are psychiatric or substance abuse health care technologies, supplies, treatments, procedures, drug therapies or devices that are determined by the Clinical Advisory Subcommittee to be:</p> <ul style="list-style-type: none"> <li>not demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;</li> <li>not approved by the U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency to be lawfully marketed for the proposed use;</li> <li>the subject of review or approval by an Institutional Review Board for the proposed use</li> </ul>

<ul style="list-style-type: none"> <li>the subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials as provided in the “Clinical Trials” section(s) of this plan.</li> </ul>	<p>except as provided in the “Clinical Trials” section(s) of this plan; or</p> <ul style="list-style-type: none"> <li>the subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials as provided in the “Clinical Trials” section(s) of this plan.</li> </ul>
---	--

Benefit Classification	Medical/Surgical Services to which the NQTL applies	Mental Health/SUD Services to which the NQTL applies
In-Network Inpatient Services	<ul style="list-style-type: none"> <li>All Medical/Surgical technologies determined to be Experimental/Investigational</li> </ul>	<ul style="list-style-type: none"> <li>All technologies determined to be Experimental/Investigational</li> </ul>
In-Network Outpatient Services	<ul style="list-style-type: none"> <li>All Medical/Surgical technologies determined to be Experimental/Investigational</li> </ul>	<ul style="list-style-type: none"> <li>All technologies determined to be Experimental/Investigational</li> </ul>

**2. Identify the factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Factors Considered: Medical/Surgical	Factors Considered: Mental Health/SUD
In-Network/ Out-of-Network Inpatient Services	<p>1. Clinical Efficacy</p> <p>Clinical efficacy is based on the evidence of clinical trials that the interventions produce the expected results under ideal controlled circumstances. Clinical effectiveness is based on the evidence of clinical trials that the interventions are</p>	<p>1. Clinical Efficacy</p> <p>Clinical efficacy is based on the evidence of clinical trials that the interventions produce the expected results under ideal controlled circumstances. Clinical effectiveness is based on the evidence of clinical trials that the interventions are</p>

	<p>considered to be effective for the general population.</p> <p>2. Clinical Safety Safety risk is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events.</p> <p>3. Appropriateness of the proposed technology</p> <p>Appropriateness is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p><b>**Note:</b> State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p>	<p>considered to be effective for the general population.</p> <p>2. Clinical Safety Safety risk is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events.</p> <p>3. Appropriateness of the proposed technology</p> <p>Appropriateness is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p><b>**Note:</b> State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p>
--	---	---

In-Network/ Out-of-Network Outpatient Services	Same as Inpatient Analysis	Same as Inpatient Analysis
--	----------------------------	----------------------------

**3. Identify the evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Evidentiary Standards and Sources: Medical/Surgical	Evidentiary Standards and Sources: MH/SUD
In-Network/ Out-of-Network Inpatient Services	<p>The Plan utilizes internally developed Coverage Policies (i.e. medical necessity criteria) and the Milliman Care Guidelines (MCG) when conducting medical necessity reviews of medical/surgical services, procedures, devices, equipment, imaging, diagnostic interventions, etc.</p> <p>The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals. The Committee's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009:</p> <p>Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.</p> <p>Level 2: Non-randomized controlled trials (an experimental study, but not an</p>	<p>The Plan utilizes Milliman Care Guidelines (MCG) when conducting medical necessity reviews of MH/SUD services and technologies and "The ASAM Criteria®" when conducting medical necessity reviews of SUD services and technologies.</p> <p>The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals. The Committee's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as set forth below in Cigna's "Levels of Scientific Evidence Table" adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009:</p> <p>Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.</p> <p>Level 2: Non-randomized controlled trials (an experimental study, but not an</p>

	<p>ideal design). Also systematic reviews and meta-analyses of non-randomized controlled trials.</p> <p>Level 3: Observational studies – e.g. cohort, case-control studies (non-experimental studies). Also systematic reviews and meta-analyses of observational studies.</p> <p>Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also systematic reviews and meta-analyses of retrospective studies.</p> <p>Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.</p>	<p>ideal design). Also systematic reviews and meta-analyses of non-randomized controlled trials.</p> <p>Level 3: Observational studies – e.g. cohort, case-control studies (non-experimental studies). Also systematic reviews and meta-analyses of observational studies.</p> <p>Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also systematic reviews and meta-analyses of retrospective studies.</p> <p>Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.</p>
In-Network/ Out-of-Network Outpatient Services	Same as Inpatient Analysis	Same as Inpatient Analysis

**4. Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and**

Experimental/Investigational Determinations Process M/S	Experimental/Investigational Determinations Process MH/SUD
<p><b>Process for Experimental/Investigational Determinations:</b></p> <p>The Clinical Advisory Subcommittee applies a consistent process in the development of evidence-based Coverage Policies for a wide variety of medical technologies. The Committee is composed of physicians and nurses, and includes specialists from assorted medical and behavioral health disciplines. The committee</p>	

reviews FDA approval/clearance status, English language peer reviewed publications as well as relevant documents prepared by specialty societies and evidence-based review centers. The committee uses principles of evidence-based medicine in its evaluation of clinical literature and in its deliberative process and in preparing published medical coverage policies. The Committee develops criteria to assist medical directors in determining whether a service/device is deemed to be medically necessary or experimental, investigational or unproven.

**Process:**

The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals.

The Committee establishes and maintains clinical guidelines and medical necessity criteria in the form of published Coverage Policies pertaining to the various medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes. This includes Coverage Policies that address medical/surgical services determined to be experimental and investigational.

While Cigna's Coverage Policies are reviewed at least once annually, re-review of Coverage Policies and/or topics for new Coverage Policies are identified through multiple channels including requests from the provider community, customers, frontline reviewers, the Clinical Advisory Subcommittee and the impetus of new, emerging and evolving technologies.

**Qualifications of those determining clinical criteria if applicable:**

The Clinical Advisory Subcommittee is chaired by a Senior Medical Director and consists of the following:

- Internal membership: Clinical Operations Nurse (RN), Senior Medical Director, Clinical Review (MD or DO), State/Regional Medical Directors (MD or DO), Designated Behavioral Health Physician (MD)
- External membership: At least four network participating practitioners (e.g., MDs, DOs)

**Process:**

The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals.

The Committee establishes and maintains clinical guidelines and medical necessity criteria in the form of published Coverage Policies pertaining to the various medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes. This includes Coverage Policies that address medical/surgical services determined to be experimental and investigational.

While Cigna's Coverage Policies are reviewed at least once annually, re-review of Coverage Policies and/or topics for new Coverage Policies are identified through multiple channels including requests from the provider community, customers, frontline reviewers, the Clinical Advisory Subcommittee and the impetus of new, emerging and evolving technologies.

**Qualifications of those determining clinical criteria if applicable:**

The Clinical Advisory Subcommittee is chaired by a Senior Medical Director and consists of the following:

- Internal membership: Clinical Operations Nurse (RN), Senior Medical Director, Clinical Review (MD or DO), State/Regional Medical Directors (MD or DO), Designated Behavioral Health Physician (MD)
- External membership: At least four network participating practitioners (e.g., MDs, DOs)

<p>Finally, these changes are reported to the UM Subcommittee and ultimately through the Quality Improvement Committee of the Board.</p> <p><b>Description of IRR process:</b> All clinicians involved in clinical decision-making participate in annual inter-rater reliability (IRR) testing to ensure high quality, evidence-based decision making and consistent application of clinical criteria across its clinical UM staff. The IRR testing benchmark is 80%, and differences in determinations are used as the basis for quarterly clinical discussion and training. For cases where scores are below benchmark, the cases will be addressed in remediation discussions for continued quality improvement.</p>	<p>Finally, these changes are reported to the UM Subcommittee and ultimately through the Quality Improvement Committee of the Board.</p> <p><b>Description of IRR process:</b> All clinicians involved in clinical decision-making participate in annual inter-rater reliability (IRR) testing to ensure high quality, evidence-based decision making and consistent application of clinical criteria across its clinical UM staff. The IRR testing benchmark is 90%, and differences in determinations are used as the basis for quarterly clinical discussion and training. For cases where scores are below benchmark, the cases will be addressed in remediation discussions for continued quality improvement.</p>
---	---

*Identify and define the factors and processes that are used to monitor and evaluate the application of Experimental/Investigational Determinations:*

Benefit Classification	Process Description: Medical/Surgical	Process Description: MH/SUD
In-Network Inpatient Services/Outpatient Services	<p>The Plan conducted a comparative analysis of the strategy, process, factors, evidentiary standards, and source information used to determine which Medical/Surgical (M/S) and Mental Health/Substance Use Disorder (MH/SUD) services are subject to experimental/investigational determinations “as written.” The Plan uses the same factors, sources, evidentiary standards, and process when rendering an experimental/investigational determination. Therefore, as-written, the methodology for experimental/investigational decision-making is applied no more stringently to MH/SUD benefits when compared to M/S benefits.</p> <p>The Plan ensures that the criteria and processes used for experimental/investigational determinations are no more stringently applied to MH/SUD than M/S benefits in operation.</p> <p>All clinicians involved in clinical decision-making participate in annual inter-rater reliability (IRR) testing to ensure high quality, evidence-based decision making and consistent application of clinical criteria across its clinical UM staff. The IRR testing benchmark for M/S clinical staff decision-making is 80% and the IRR testing benchmark for MH/SUD clinical staff decision-making is 90%. Differences in determinations are used as the basis for quarterly clinical discussion and training. For cases where scores are below benchmark, the cases will be addressed in remediation discussions for continued quality improvement.</p>	

	<p><b>Inter-Rater Reliability Testing Results:</b></p> <table border="1"> <tr> <th data-bbox="407 323 919 426">Inter-rater reliability score clinical reviewers (M/S) 2021:</th><th data-bbox="919 323 1443 426">Inter-rater reliability score clinical reviewers (MH/SUD) 2021:</th></tr> <tr> <td data-bbox="407 426 919 493">93%</td><td data-bbox="919 426 1443 493">97%</td></tr> </table>	Inter-rater reliability score clinical reviewers (M/S) 2021:	Inter-rater reliability score clinical reviewers (MH/SUD) 2021:	93%	97%
Inter-rater reliability score clinical reviewers (M/S) 2021:	Inter-rater reliability score clinical reviewers (MH/SUD) 2021:				
93%	97%				

**5. Provide the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.**

<p>In-Network and Out-of-Network Inpatient Services/Outpatient Services</p>	<p>The underlying processes, strategies, evidentiary standards and other factors used to apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA for the following reasons:</p> <ol style="list-style-type: none"> <li>1. The factors, sources, and evidentiary standards used to determine experimental/investigational services are the same.</li> <li>2. As written, the same process is employed for experimental/investigational determinations and the clinical advisory committee is responsible for developing and maintaining clinical guidelines and medical necessity criteria across M/S benefits and MH/SUD benefits.</li> <li>3. In-operation, the Plan performs in-operation data assessments to ensure that the underlying methodology for experimental/investigational determinations is applied no more stringently to MH/SUD benefits when compared to M/S benefits.</li> </ol> <p>Findings/Conclusion: The findings of the comparative analysis reveal that the methodology for experimental/investigational determinations for MH/SUD benefits is comparable to, and applied no more stringently than, the methodology for experimental/investigational determinations for M/S benefits. When reviewing the inter-rater reliability testing scores for clinical-decision making in 2021, medical clinical reviewers' and behavioral health clinical reviewers' average IRR scores met the relative benchmarks of 80% and 90% respectively. Medical clinical reviewers scored an average IRR score of 93% for 2021, while behavioral health clinical reviewers scored an average IRR score of 97%. Inter-rater reliability testing is employed to ensure high quality, evidence-based decision making and consistent application of clinical criteria across its clinical UM staff. Since behavioral health clinical reviewers achieved an average score of 97% and medical clinical reviewers</p>
---	---

	<p>achieved an average score of 93%, there is evidence that reviewers apply consistent evidence-based decision making when rendering medical necessity determinations. Thus, the underlying processes, strategies, evidentiary standards and other factors as-written and in-operation used to apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA.</p>
--	--

<b>Non-Quantitative Treatment Limitation (NQTL) Analysis Index</b>	
<b>Non-Quantitative Treatment Limitation</b>	Medical Necessity Criteria Development Strategy
<b>Plan Type(s) Applicable</b>	Cigna + Oscar
<b>Responsible Business Teams</b>	Clinical
<b>Names of Person(s) Responsible for Analysis Formation</b>	Insiya Taj, MPH, Associate, UM Optimization, (Over 3 years experience in healthcare and clinical research) Marco Fossati-Bellani, MD, MPH, Senior Medical Director, UM Mimi Shim, MPH, RN, Associate Clinical Manager, Clinical Policy
<b>Last Update</b>	7/1/2022
<b>Reviewers</b>	Alexandra Rubino, Associate Director, MHP (Over 4 years experience in Mental Health Parity reporting and operational compliance)



**Non-Quantitative Treatment Limitation (NQL) Analysis for the Mental Health Parity  
and Addiction Equity Act (MHPAEA)**

**Medical Necessity Criteria Development Strategy**

- 1. The specific plan or coverage terms or other relevant terms regarding Prior Authorization and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification**

Medical/Surgical Terms	Mental Health/Substance Use Disorder Terms
<p><b>Definition:</b></p> <p>When conducting medical necessity reviews of medical/surgical services, Plan Medical Directors and licensed physician reviewers apply the definition of “medical necessity” set forth in the governing plan instrument or the definition required by state law. Notwithstanding the above, Cigna's standard definition of “medical necessity” is as follows:</p> <p><b>Medically Necessary/Medical Necessity</b></p> <p>Medically Necessary Covered Services and Supplies are those determined by the Medical Director to be:</p> <ul style="list-style-type: none"> <li>• required to diagnose or treat an illness, injury, disease or its symptoms;</li> <li>• in accordance with generally accepted standards of medical practice;</li> <li>• clinically appropriate in terms of type, frequency, extent, site and duration;</li> <li>• not primarily for the convenience of the patient, Physician or other health care provider; and</li> <li>• rendered in the least intensive setting that is appropriate for the delivery of the services and supplies. Where applicable, the Medical Director may compare the cost-effectiveness of alternative services, settings or supplies when determining least intensive setting.</li> </ul>	<p><b>Definition:</b></p> <p>When conducting medical necessity reviews of MH/SUD services, Plan Medical Directors and licensed physician reviewers apply the definition of “medical necessity” set forth in the governing plan instrument or the definition required by state law. Notwithstanding the above, Cigna's standard definition of “medical necessity” is as follows:</p> <p><b>Medically Necessary/Medical Necessity</b></p> <p>Medically Necessary Covered Services and Supplies are those determined by the Medical Director to be:</p> <ul style="list-style-type: none"> <li>• required to diagnose or treat an illness, injury, disease or its symptoms;</li> <li>• in accordance with generally accepted standards of medical practice;</li> <li>• clinically appropriate in terms of type, frequency, extent, site and duration;</li> <li>• not primarily for the convenience of the patient, Physician or other health care provider; and</li> <li>• rendered in the least intensive setting that is appropriate for the delivery of the services and supplies. Where applicable, the Medical Director may compare the cost-effectiveness of alternative services, settings or supplies when determining least intensive setting.</li> </ul>

Benefit Classification	Medical/Surgical Services to which the NQTL applies	Mental Health/SUD Services to which the NQTL applies
In-Network/Out-of-Network Inpatient Services	<ul style="list-style-type: none"> <li>All Medical/Surgical technologies subject to Utilization Management</li> </ul>	<ul style="list-style-type: none"> <li>All MH/SUD technologies subject to Utilization Management</li> </ul>
In-Network/Out-of-Network Outpatient Services	<ul style="list-style-type: none"> <li>All Medical/Surgical technologies subject to Utilization Management</li> </ul>	<ul style="list-style-type: none"> <li>All MH/SUD technologies subject to Utilization Management</li> </ul>

**2. Identify the factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Factors Considered: Medical/Surgical	Factors Considered: Mental Health/SUD
In-Network/Out-of-Network Inpatient Services	<p><b>Factors for medical necessity criteria development:</b></p> <ol style="list-style-type: none"> <li>Clinical efficacy of the proposed treatment or service  Clinical efficacy is based on the evidence of clinical trials that the interventions produce the expected results under ideal controlled circumstances. Clinical effectiveness is based on the evidence of clinical trials that the interventions are considered to be effective for the general population.</li> <li>Safety Risk</li> </ol>	<p><b>Factors for medical necessity criteria development:</b></p> <ol style="list-style-type: none"> <li>Clinical efficacy of the proposed treatment or service  Clinical efficacy is based on the evidence of clinical trials that the interventions produce the expected results under ideal controlled circumstances. Clinical effectiveness is based on the evidence of clinical trials that the interventions are considered to be effective for the general population.</li> <li>Safety Risk</li> </ol>

	<p>Safety risk is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events.</p> <p>3. Appropriateness of the proposed technology</p> <p>Appropriateness is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p>	<p>Safety risk is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events.</p> <p>3. Appropriateness of the proposed technology</p> <p>Appropriateness is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p>
In-Network/Out-of-Network Outpatient Services	Same as Inpatient Analysis	Same as Inpatient Analysis



**3. Identify the evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Evidentiary Standards and Sources: Medical/Surgical	Evidentiary Standards and Sources: MH/SUD
In-Network/ Out-of-Network Inpatient Services	<p>The Plan utilizes internally developed Coverage Policies (i.e. medical necessity criteria) and the Milliman Care Guidelines (MCG) when conducting medical necessity reviews of medical/surgical services, procedures, devices, equipment, imaging, diagnostic interventions, etc.</p> <p>The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals. The Committee’s evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009:</p> <p>Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.</p> <p>Level 2: Non-randomized controlled trials (an experimental study, but not an ideal design). Also systematic reviews and meta-analyses of non-randomized controlled trials.</p> <p>Level 3: Observational studies – e.g. cohort, case-control studies (non-experimental studies). Also systematic</p>	<p>The Plan utilizes Milliman Care Guidelines (MCG) when conducting medical necessity reviews of MH/SUD services and technologies and “The ASAM Criteria®” when conducting medical necessity reviews of SUD services and technologies.</p> <p>The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals. The Committee’s evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as set forth below in Cigna’s “Levels of Scientific Evidence Table” adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009:</p> <p>Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.</p> <p>Level 2: Non-randomized controlled trials (an experimental study, but not an ideal design). Also systematic reviews and meta-analyses of non-randomized controlled trials.</p> <p>Level 3: Observational studies – e.g. cohort, case-control studies (non-experimental studies). Also systematic</p>

	<p>reviews and meta-analyses of observational studies.</p> <p>Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also systematic reviews and meta-analyses of retrospective studies.</p> <p>Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.</p>	<p>reviews and meta-analyses of observational studies.</p> <p>Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also systematic reviews and meta-analyses of retrospective studies.</p> <p>Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.</p>
In-Network/ Out-of-Network Outpatient Services	Same as Inpatient Analysis	Same as Inpatient Analysis

**4. Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and**

*Briefly describe the processes by which Medical Necessity Criteria Development Strategy is applied:*

Process M/S	Process MH/SUD
-------------	----------------

**Process:**

The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals.

The Committee establishes and maintains clinical guidelines and medical necessity criteria in the form of published Coverage Policies pertaining to the various medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes. This includes Coverage Policies that address medical/surgical services determined to be experimental and investigational.

While Cigna's Coverage Policies are reviewed at least once annually, re-review of Coverage Policies and/or topics for new Coverage Policies are identified through multiple channels including requests from the provider community, customers, frontline reviewers, the Clinical Advisory Subcommittee and the impetus of new, emerging and evolving technologies.

**Qualifications of those determining clinical criteria if applicable:**

The Clinical Advisory Subcommittee is chaired by a Senior Medical Director and consists of the following:

- Internal membership: Clinical Operations Nurse (RN), Senior Medical Director, Clinical Review (MD or DO), State/Regional Medical Directors (MD or DO), Designated Behavioral Health Physician (MD)

- External membership: At least four network participating practitioners (e.g., MDs, DOs)

Finally, these changes are reported to the UM Subcommittee and ultimately through the Quality Improvement Committee of the Board.

**Description of IRR process:** All clinicians involved in clinical decision-making participate in annual inter-rater reliability (IRR) testing to ensure high quality, evidence-based decision making and consistent

**Process:**

The Clinical Advisory Subcommittee conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals.

The Committee establishes and maintains clinical guidelines and medical necessity criteria in the form of published Coverage Policies pertaining to the various medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes. This includes Coverage Policies that address medical/surgical services determined to be experimental and investigational.

While Cigna's Coverage Policies are reviewed at least once annually, re-review of Coverage Policies and/or topics for new Coverage Policies are identified through multiple channels including requests from the provider community, customers, frontline reviewers, the Clinical Advisory Subcommittee and the impetus of new, emerging and evolving technologies.

**Qualifications of those determining clinical criteria if applicable:**

The Clinical Advisory Subcommittee is chaired by a Senior Medical Director and consists of the following:

- Internal membership: Clinical Operations Nurse (RN), Senior Medical Director, Clinical Review (MD or DO), State/Regional Medical Directors (MD or DO), Designated Behavioral Health Physician (MD)

- External membership: At least four network participating practitioners (e.g., MDs, DOs)

Finally, these changes are reported to the UM Subcommittee and ultimately through the Quality Improvement Committee of the Board.

**Description of IRR process:** All clinicians involved in clinical decision-making participate in annual inter-rater reliability (IRR) testing to ensure high quality, evidence-based decision making and consistent

<p>application of clinical criteria across its clinical UM staff. The IRR testing benchmark is 80%, and differences in determinations are used as the basis for quarterly clinical discussion and training. For cases where scores are below benchmark, the cases will be addressed in remediation discussions for continued quality improvement.</p>	<p>application of clinical criteria across its clinical UM staff. The IRR testing benchmark is 90%, and differences in determinations are used as the basis for quarterly clinical discussion and training. For cases where scores are below benchmark, the cases will be addressed in remediation discussions for continued quality improvement.</p>
---	---

*Identify and define the factors and processes that are used to monitor and evaluate the application of Medical Necessity Criteria Development Strategy:*

<b>Benefit Classification</b>	<b>Process Description: Medical/Surgical</b>	<b>Process Description: MH/SUD</b>
In-Network and Out-of-Network Inpatient Services/Outpatient Services	<p>The Plan conducted a comparative analysis of the strategy, process, factors, evidentiary standards, and source information used to determine medical necessity criteria development for medical/surgical benefits (M/S) and mental health/substance use disorder (MH/SUD) benefits “as written.” The Plan uses the same factors, sources, evidentiary standards, and process when developing medical necessity criteria. Therefore, as-written, the methodology for medical necessity is applied no more stringently to MH/SUD benefits when compared to M/S benefits.</p> <p>The Plan ensures that the criteria and processes used for medical necessity determinations are no more stringently applied to MH/SUD than M/S benefits in operation.</p> <p>All clinicians involved in clinical decision-making participate in annual inter-rater reliability (IRR) testing to ensure high quality, evidence-based decision making and consistent application of clinical criteria across its clinical UM staff. The IRR testing benchmark for M/S clinical staff decision-making is 80% and the IRR testing benchmark for MH/SUD clinical staff decision-making is 90%. Differences in determinations are used as the basis for quarterly clinical discussion and training. For cases where scores are below benchmark, the cases will be addressed in remediation discussions for continued quality improvement.</p> <p><b>Inter-Rater Reliability Testing Results:</b></p>	

	<b>Inter-rater reliability score clinical reviewers (M/S) 2021:</b>	<b>Inter-rater reliability score clinical reviewers (MH/SUD) 2021:</b>
	<b>93%</b>	<b>97%</b>

**5. Provide the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.**

In-Network and Out-of-Network Inpatient Services/Outpatient Services	<p>The underlying processes, strategies, evidentiary standards and other factors used to apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA for the following reasons:</p> <ol style="list-style-type: none"> <li>1. The factors, sources, and evidentiary standards used to develop medical necessity criteria are the same.</li> <li>2. As written, the same process is employed when developing medical necessity criteria and the clinical advisory committee is responsible for developing and maintaining clinical guidelines and medical necessity criteria across M/S and MH/SUD benefits.</li> <li>3. In-operation, the Plan performs in-operation data assessments to ensure that the underlying methodology for developing medical necessity criteria is applied no more stringently to MH/SUD services when compared to M/S services.</li> </ol> <p>Findings/Conclusion: The findings of the comparative analysis reveal that the methodology for medical necessity criteria development for MH/SUD benefits is comparable to, and applied no more stringently than, the methodology for medical necessity criteria for M/S benefits. When reviewing the inter-rater reliability testing scores for clinical-decision making in 2021, medical reviewers' and behavioral health reviewers' average IRR scores met the relative benchmarks of 80% and 90% respectively. Medical clinical reviewers scored an average IRR score of 93% for 2021, while behavioral health clinical reviewers scored an average IRR score of 97%. Inter-rater reliability testing is employed to ensure high quality, evidence-based decision making and consistent application of clinical criteria across its clinical UM staff. Since behavioral health clinical reviewers achieved an average score of 97% and medical clinical reviewers achieved an average score of 93%, there is evidence</p>
--	--

	<p>that reviewers apply consistent evidence-based decision making when rendering medical necessity determinations. Thus, the underlying processes, strategies, evidentiary standards and other factors as-written and in-operation used to apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA.</p>
--	--

<b>Non-Quantitative Treatment Limitation (NQTL) Analysis Index</b>	
<b>Non-Quantitative Treatment Limitation</b>	Prior Authorization
<b>Plan Type(s) Applicable</b>	Cigna + Oscar
<b>Responsible Business Teams</b>	Clinical
<b>Names of Person(s) Responsible for Analysis Formation</b>	Insiya Taj, MPH, Associate, UM Optimization, (Over 3 years experience in healthcare and clinical research) Marco Fossati-Bellani, MD, MPH, Senior Medical Director, UM
<b>Last Update</b>	7/1/2022
<b>Reviewers</b>	Alexandra Rubino, Associate Director, MHP (Over 4 years experience in Mental Health Parity reporting and operational compliance)



**Non-Quantitative Treatment Limitation (NQTL) Analysis for the Mental Health Parity and Addiction Equity Act (MHPAEA)**

**Prior Authorization**

1. Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply:

Medical/Surgical Terms	Mental Health/Substance Use Disorder Terms
<b>Definition:</b> The Plan defines prior authorization as the process by which the utilization review agent determines the medical necessity of otherwise covered health care services prior to the rendering of such health care services including, but not limited to, preadmission review, pretreatment review, utilization, and case management.	<b>Definition:</b> The Plan defines prior authorization as the process by which the utilization review agent determines the medical necessity of otherwise covered health care services prior to the rendering of such health care services including, but not limited to, preadmission review, pretreatment review, utilization, and case management.

Benefit Classification	Medical/Surgical Services to which the NQTL applies	Mental Health/SUD Services to which the NQTL applies
In-Network/Out-of-Network Inpatient Services	<p>All inpatient services are subject to this NQTL.</p> <ul style="list-style-type: none"> <li>● Acute/Elective Hospital</li> <li>● Hospice</li> <li>● Long-Term Acute Care</li> <li>● Rehabilitation, Acute/Subacute</li> <li>● Skilled Nursing Facility</li> </ul>	<p>All inpatient services are subject to this NQTL.</p> <ul style="list-style-type: none"> <li>● All Inpatient Admissions (Non-emergent) <ul style="list-style-type: none"> <li>○ Acute hospital</li> <li>○ Rehabilitation, Acute/Subacute</li> <li>○ Residential treatment</li> </ul> </li> </ul>
In-Network/Out-of-Network Outpatient Services	<ul style="list-style-type: none"> <li>● Physician-Administered Drugs</li> <li>● Certain DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) such as oxygen, CPAP, and diabetic supplies</li> <li>● Home Health Care Services</li> <li>● Advanced Imaging</li> </ul>	<ul style="list-style-type: none"> <li>● Adaptive Behavior Assessment &amp; Therapy</li> <li>● Applied behavior analysis (ABA)</li> <li>● Detoxification programs</li> <li>● Outpatient psychiatric testing</li> <li>● Partial hospitalization treatment</li> <li>● Transcranial magnetic stimulation (TMS)</li> </ul>

	<ul style="list-style-type: none"> <li>• Diagnostic Tests &amp; Evaluations, Laboratory Procedures</li> <li>• Outpatient Treatments/Procedures</li> <li>• Non-Emergency Transportation</li> <li>• Unlisted Procedures</li> </ul>	
--	--	--

**2. Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits:**

<b>Benefit Classification</b>	<b>Factors Considered: Medical/Surgical</b>	<b>Factors Considered: Mental Health/SUD</b>
In-Network/ Out-of-Network Inpatient Services	<ol style="list-style-type: none"> <li>1. Clinical appropriateness</li> <li>2. Safety risk</li> <li>3. Cost</li> </ol>	<ol style="list-style-type: none"> <li>1. Clinical appropriateness</li> <li>2. Safety risk</li> <li>3. Cost</li> </ol>
In-Network/ Out-of-Network Outpatient Services	<ol style="list-style-type: none"> <li>1. Cost variability</li> <li>2. Denial rate</li> <li>3. Cost percentile</li> <li>4. Safety risk</li> <li>5. New/emerging service/technology</li> <li>6. Clinical appropriateness</li> </ol>	<ol style="list-style-type: none"> <li>1. Cost variability</li> <li>2. Denial rate</li> <li>3. Cost percentile</li> <li>4. Safety risk</li> <li>5. New/emerging service/technology</li> <li>6. Clinical appropriateness</li> </ol>

**3. Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits:**

Benefit Classification	Evidentiary Standards and Sources: Medical/Surgical	Evidentiary Standards and Sources: MH/SUD
In-Network/ Out-of-Network Inpatient Services	<p>1. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria</li> </ul>	<p>1. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria</li> </ul>

	<p>WPATH guidelines.</p> <ul style="list-style-type: none"> <li>As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>Plan Clinical Guidelines</li> <li>MCG</li> <li>ASAM (SUD only)</li> <li>Hayes</li> <li>UpToDate</li> <li>National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>The US National Library of Medicine;</li> <li>Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>Published scientific evidence;</li> <li>In consultation with medical experts and providers who have</li> </ul>	<p>WPATH guidelines.</p> <ul style="list-style-type: none"> <li>As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>Plan Clinical Guidelines</li> <li>MCG</li> <li>ASAM (SUD only)</li> <li>Hayes</li> <li>UpToDate</li> <li>National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>The US National Library of Medicine;</li> <li>Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>Published scientific evidence;</li> <li>In consultation with medical experts and providers who have</li> </ul>
--	---	---

	<p>expertise in the particular area of the services (e.g., board-certified physician specialists).</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul> <p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p> <p>2. <b>Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered. If there is a less restrictive level of care available to meet the member's health needs, prior authorization may be applied to ensure the member receives the least restrictive level of care that is clinically appropriate.</p> <p>Sources: National societies and health</p>	<p>expertise in the particular area of the services (e.g., board-certified physician specialists).</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul> <p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p> <p>2. <b>Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered. If there is a less restrictive level of care available to meet the member's health needs, prior authorization may be applied to ensure the member receives the least restrictive level of care that is clinically appropriate.</p> <p>Sources: National societies and health</p>
--	---	---

	<p>agencies, Clinical criteria<sup>1</sup>, Clinical evidence<sup>2</sup></p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N.</i></p>	<p>agencies, Clinical criteria<sup>3</sup>, Clinical evidence<sup>4</sup></p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N.</i></p>
--	---	---

<sup>1</sup> Clinical criteria includes: Plan Clinical Guidelines, MCG, ASAM (SUD only), Hayes, UpToDate, National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)

<sup>2</sup> Clinical evidence: The US National Library of Medicine; Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN); Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH); Published scientific evidence; In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).

<sup>3</sup> Clinical criteria includes: Plan Clinical Guidelines, MCG, ASAM (SUD only), Hayes, UpToDate, National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)

<sup>4</sup> Clinical evidence: The US National Library of Medicine; Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN); Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH); Published scientific evidence; In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).

	<p><i>The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</i></p> <p><b>3. High Cost</b></p> <p>Evidentiary Standard: The mean cost of an inpatient episode of care is &gt;\$12,000</p> <p>Source: Claims data</p>	<p><i>The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</i></p> <p><b>3. High Cost</b></p> <p>Evidentiary Standard: The mean cost of an inpatient episode of care is &gt;\$12,000</p> <p>Source: Claims data</p>
In-Network/ Out-of-Network Outpatient Services	<p><b>1. Cost variability</b> is defined as the cost per episode of service (service units X unit cost) that trigger 2x the mean of other outpatient services and provided to a minimum of twenty unique Plan members. Outpatient services are subject to variability in cost per episode of service relative to other services within the classification of benefits. For each service, the Plan calculates the Average Annual Allowed Amount per Unique Patient with Outpatient Claim Events for that Primary Service.</p> <p>Source: Claims data</p> <p>Threshold: Cost per episode of service that triggers 2x the mean of other outpatient services.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Musculoskeletal Surgery   Joint arthroscopy / arthroplasty /</li> </ul>	<p><b>1. Cost variability</b> is defined as the cost per episode of service (service units X unit cost) that trigger 2x the mean of other outpatient services and provided to a minimum of twenty unique Plan members. Outpatient services are subject to variability in cost per episode of service relative to other services within the classification of benefits. For each service, the Plan calculates the Average Annual Allowed Amount per Unique Patient with Outpatient Claim Events for that Primary Service.</p> <p>Source: Claims data</p> <p>Threshold: Cost per episode of service that triggers 2x the mean of other outpatient services.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Musculoskeletal Surgery   Joint arthroscopy / arthroplasty /</li> </ul>

	<p>arthrodesis Cost variability applies to this service category. Cost variability is 5x the mean of other outpatient services.</p> <ul style="list-style-type: none"> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient Psychiatric Testing Cost variability applies to this service category. Cost variability is 2.9x the mean of other outpatient services.</li> </ul> <p><b>2. Denial rate</b> is defined as the percentage of prior authorization requests that are denied by the Plan.</p> <p>Source: Prior authorization data</p> <p>Threshold: &gt;10%</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Skin Treatments &amp; Procedures   UV / Laser therapy Denial rate applies to this service category. Denial rate is 70% for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Partial Hospitalization Denial rate applies to this service category. Denial rate is 60% for this service category.</li> </ul> <p><b>3. Cost percentile</b> is defined as the average cost per claim event for a particular outpatient service relative to other services within the classification of benefits.</p>	<p>arthrodesis Cost variability applies to this service category. Cost variability is 5x the mean of other outpatient services.</p> <ul style="list-style-type: none"> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient Psychiatric Testing Cost variability applies to this service category. Cost variability is 2.9x the mean of other outpatient services.</li> </ul> <p><b>2. Denial rate</b> is defined as the percentage of prior authorization requests that are denied by the Plan.</p> <p>Source: Prior authorization data</p> <p>Threshold: &gt;10%</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Skin Treatments &amp; Procedures   UV / Laser therapy Denial rate applies to this service category. Denial rate is 70% for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Partial Hospitalization Denial rate applies to this service category. Denial rate is 60% for this service category.</li> </ul> <p><b>3. Cost percentile</b> is defined as the average cost per claim event for a particular outpatient service relative to other services within the classification of benefits.</p>
--	---	---

	<p>Source: Claims data</p> <p>Threshold: <math>\geq</math> 85th Percentile</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>● Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Digestive Treatments &amp; Procedures   Bariatric surgery Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> <li>● Benefit: Mental Health/Substance Use Disorder Service: Outpatient psychiatric testing Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> </ul> <p><b>4. Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health agencies, Clinical criteria, Clinical evidence</p> <ul style="list-style-type: none"> <li>● Centers for Medicare &amp; Medicaid Services</li> <li>● World Health Organization</li> <li>● Institute For Safe Medication Practices</li> <li>● U.S. Food and Drug</li> </ul>	<p>Source: Claims data</p> <p>Threshold: <math>\geq</math> 85th Percentile</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>● Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Digestive Treatments &amp; Procedures   Bariatric surgery Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> <li>● Benefit: Mental Health/Substance Use Disorder Service: Outpatient psychiatric testing Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> </ul> <p><b>4. Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health agencies, Clinical criteria, Clinical evidence</p> <ul style="list-style-type: none"> <li>● Centers for Medicare &amp; Medicaid Services</li> <li>● World Health Organization</li> <li>● Institute For Safe Medication Practices</li> <li>● U.S. Food and Drug</li> </ul>
--	--	--

	<p>Administration</p> <ul style="list-style-type: none"> <li>• Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>• Treatments that increase the likelihood of adverse health effects</li> <li>• Services that increase the likelihood of perioperative morbidity and mortality</li> <li>• Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>• Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>• Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017</i> (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> </ul>	<p>Administration</p> <ul style="list-style-type: none"> <li>• Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>• Treatments that increase the likelihood of adverse health effects</li> <li>• Services that increase the likelihood of perioperative morbidity and mortality</li> <li>• Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>• Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>• Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017</i> (<a href="http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf">http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf</a>).</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> </ul>
--	--	--

	<ul style="list-style-type: none"> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Surgical procedures at risk for infection and complications (e.g., gastrectomy, hip replacement)</li> <li>• Advanced radiology procedures with exposure to radiation (e.g., CT, MRI, nuclear medicine)</li> <li>• Physician-administered drugs due to the risk for adverse effects and contraindications (e.g., chemotherapeutic agents)</li> </ul> <p><b>5. New/ Emerging Service/ Technology</b> is defined as any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven. Services that are not accepted as the standard medical treatment of the condition being treated are considered “new and emerging services and technologies.” This includes any health care service, testing, procedure, treatment, device, or prescription drug that:</p>	<ul style="list-style-type: none"> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Surgical procedures at risk for infection and complications (e.g., gastrectomy, hip replacement)</li> <li>• Advanced radiology procedures with exposure to radiation (e.g., CT, MRI, nuclear medicine)</li> <li>• Physician-administered drugs due to the risk for adverse effects and contraindications (e.g., chemotherapeutic agents)</li> </ul> <p><b>5. New/ Emerging Service/ Technology</b> is defined as any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven. Services that are not accepted as the standard medical treatment of the condition being treated are considered “new and emerging services and technologies.” This includes any health care service, testing, procedure, treatment, device, or prescription drug that:</p>
--	--	--

	<ul style="list-style-type: none"> <li>• Is not accepted as standard medical treatment of the condition; or</li> <li>• Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; or</li> <li>• Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or</li> <li>• Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; or</li> <li>• Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> </ul>	<ul style="list-style-type: none"> <li>• Is not accepted as standard medical treatment of the condition; or</li> <li>• Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; or</li> <li>• Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or</li> <li>• Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; or</li> <li>• Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> </ul>
--	---	---

	<ul style="list-style-type: none"> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Genetic, biomarker and molecular tests</li> <li>• Medical devices and implants</li> <li>• Novel therapies (e.g., gene therapy, CAR T-Cell therapy)</li> </ul> <p>6. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking</p>	<ul style="list-style-type: none"> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Genetic, biomarker and molecular tests</li> <li>• Medical devices and implants</li> <li>• Novel therapies (e.g., gene therapy, CAR T-Cell therapy)</li> </ul> <p>6. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking</p>
--	---	---

	<p>into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>● As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>● As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>● As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul>	<p>into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>● As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>● As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>● As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul>
--	---	---

	<p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul>	<p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Physical Therapy/Occupational Therapy</li> <li>• Gender affirming surgeries</li> <li>• Confirming member has undergone hormone therapy and counseling</li> <li>• Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>• Physician-administered drugs</li> <li>• Level of care setting</li> </ul>
	<p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p>	<p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p>

**4. Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the**



processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and

*For each MH/SUD and M/S benefit subject to Prior Authorization, identify which of the factor(s) in Step 3 were met:*

**In-Network/Out-of-Network Outpatient M/S**

Service	Cost variability	Denial rate	Cost percentile	Safety risk	New/ Emerging Service/ Technology	Clinical Appropriateness
Physician-Administered Drugs		X		X	X	X
DMEPOS		X	X		X	X
Home Health Care Services		X				X
Advanced Imaging		X		X		
Diagnostic Tests & Evaluations, Laboratory Procedures		X	X		X	X
Treatments/ Procedures	X	X	X	X	X	X
Non-Emergency Transportation		X	X			
Unlisted Procedures	X	X		X	X	

**In-Network/Out-of-Network Outpatient MH/SUD**

Service	Cost variability	Denial rate	Cost percentile	Safety risk	New/ Emerging	Clinical Appropriateness
---------	------------------	-------------	-----------------	-------------	---------------	--------------------------

					Service/ Technology	
Adaptive Behavior Assessment & Therapy	X					X
Applied behavior analysis (ABA)	X					X
Detoxification programs	X		X			
Outpatient psychiatric testing	X	X	X			
Partial hospitalization treatment	X	X				X
Transcranial magnetic stimulation (TMS)	X					X

Prior Authorization Process M/S	Prior Authorization Process MH/SUD
<p>The prior-authorization process is part of the Utilization Review (UR) activities performed by the Plan. Utilization Review is the assessment performed to determine if a medical, behavioral, or pharmacy service meets the Plan's medical necessity criteria for coverage. The Plan maintains a list of services that require prior authorization. This list is available on request by phone, by provider portal, or via the published provider manual. Authorizations can be submitted via phone, fax, or online through Oscar's provider portal. When a prior authorization request is submitted, it is reviewed by licensed clinicians to determine if the request meets medical necessity. Clinicians utilize the Plan's policies and established, evidence based clinical criteria to determine if the request meets coverage determinations and/or medical necessity. Licensed clinicians (e.g., physicians and nurses) review authorization requests; only board certified physicians can make adverse determinations.</p>	

The Plan requires the requesting provider to submit the following information when requesting an authorization:

- Member information (name, Plan ID, date of birth).
- Facility (if applicable).
- Referring and treating provider name, National Provider Identifier (NPI), and Taxpayer Identification Number (TIN).
- Treatment information including diagnostic and/or procedure codes, requested amount and length of treatment(s).

Both the providers and members are notified of the determination consistent with state, federal and accreditation requirements and applicable appeal rights are provided.

*For each committee used to determine which benefits to subject to Prior Authorization, describe the committee's purpose, composition and member qualifications, and process:*

Committee Information M/S	Committee Information MH/SUD
<p>The OMC Board of Directors has the ultimate authority and responsibility for the quality of care and services delivered to its members. The Board of Directors provides strategic planning and direction, budget approval, and staff allocation for the UM Department. The Board of Directors assigns day-to-day responsibility for implementation of the UM Program to the UM Subcommittee, which is a subcommittee of the Quality Improvement Committee. The Board of Directors oversees the implementation of and adherence to the UM Program through the UM Subcommittee. The UM Subcommittee reports to the Quality Improvement Committee at a minimum of once per quarter, per year. The UM Program and Annual Program Evaluation are approved at the UM Subcommittee portion of the Quality Improvement Committee meeting. Minutes conveying this approval are submitted to the Board of Directors, who approve the actions of the Quality Improvement Committee. The Board of Directors delegates the responsibility for the oversight and operations of the UM Program to the Chief Medical Director (CMO). The CMO oversees the UM Program with input from the Quality Improvement Committee, and support from members of the UM staff (clinical and non-clinical).</p> <p>As noted above, the UM Subcommittee is a sub-committee to the Quality Improvement Committee. A senior-level physician chairs the UM Subcommittee with representation from licensed physicians (MD, DO) and licensed nurses (RN). Key health plan functions are represented at the meeting, including participation of the behavioral health designated physician (MD, clinical PhD, PsyD). Additional internal department representatives attend based on identified needs. The UM Subcommittee meets quarterly, or more frequently as necessary.</p> <p>The UM Subcommittee undertakes, but is not limited to, the following ongoing activities:</p> <ul style="list-style-type: none"> <li>• Evaluates and refines the UM Program through analysis of curated objective metrics and subjective feedback from members and Providers, making recommendations for intervention when indicated.</li> </ul>	

- Reviews and approves modifications to the UM Program as indicated by operational needs and/or to meet regulatory and accreditation compliance.
- Reviews and approves written Clinical Criteria and protocols for the determination of medical necessity and appropriateness of healthcare procedures and services.
- Reviews and approves modifications to the healthcare procedures and services subject to Prior Authorization.

*Briefly describe the processes by which prior authorization is applied:*

Benefit Classification	Process Description: Medical/Surgical	Process Description: MH/SUD
In-Network Inpatient Services/Outpatient Services	<p><b>Timelines and deadlines for review and approvals:</b></p> <ul style="list-style-type: none"> <li>• Standard: Decisions are made within the lesser of 2 business days or 72 hours upon receipt of a complete request.</li> <li>• Urgent: Decisions are made within the lesser of 2 business days or 72 hours upon receipt of a complete request.</li> </ul> <p><b>Forms and/or other information required to be submitted by the provider:</b> The Plan will collect only information necessary to make a utilization review determination and will not routinely require providers to code requests or submit medical records for all patients. During prior and concurrent reviews, only the necessary and relevant section of medical records will be requested, as needed to verify medical necessity.</p> <p>All records are maintained electronically in the Plan's PHI-compliant systems. Any PHI is protected as per the Plan's HIPAA and PHI protection policies. In no event will information obtained by the Plan be used by persons other than health care professionals, medical record technologists, or personnel who have been appropriately trained.</p> <p><b>UM manuals and any other documentation of UM processes that are relied upon to make a determination:</b> The Plan conducts a full investigation of each request, taking into consideration all documents, clinical records, and other information submitted. In all cases, nurse and physician reviewers adhere to the clinical criteria and guidelines outlined in the Plan's UM Plan.</p> <p><b>Qualifications of UM reviewers:</b> Licensed clinicians (e.g., physicians and nurses) review authorization requests; only board certified physicians can make adverse determinations. Clinical reviewers must have an active unrestricted professional license in a state or territory of the United States, and within scope of practice relevant to the clinical area they are reviewing.</p>	

	<p><b>Minimum standards to issue a denial (e.g., sign-off from a physician with relevant board certification):</b></p> <p>When a prior authorization request is submitted, it is reviewed by licensed clinicians to determine if the request meets medical necessity. Clinicians utilize the Plan's policies and established, evidence based clinical criteria to determine if the request meets coverage determinations and/or medical necessity. Licensed clinicians (e.g., physicians and nurses) review authorization requests; only board certified physicians can make adverse determinations.</p>
--	--

*Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization*

Benefit Classification	Process Description: Medical/Surgical	Process Description: MH/SUD
In-Network Inpatient Services/Outpatient Services	<p>The Plan ensures that processes, strategies, and evidentiary standards used in applying prior authorization is comparable and no more stringently applied to mental health/substance use disorder (MH/SUD) benefits and medical/surgical (M/S) benefits, both as written and in operation. This includes the prior authorization request process, governance of the prior authorization list, and factors, sources, and evidentiary standards that contribute to the development of the prior authorization list.</p> <p>The factors, sources, evidentiary standards, and process for prior authorization decisions are the same across M/S and MH/SUD benefits. The processes for pre-service reviews are similar for M/S and MH/SUD. For both, medical necessity review is conducted by licensed clinicians, and medical necessity determinations are based on whether the treatment/services are consistent with the member's coverage, medically appropriate, and consistent with evidence-based practice. Prior Authorization processes for M/S benefits and mental health/substance use disorder benefits follow state, federal, or accreditation timeframe requirements. Therefore, as-written, prior authorization is applied no more stringently to MH/SUD benefits when compared to M/S benefits.</p> <p>Operationally, the Plan performs in-operation data assessments to ensure that factors, sources, and evidentiary standards are applied in a consistent manner. For UM, the Plan reviews rates of denials for pre-service review across benefit categories and compares these denial rates for M/S services against MH/SUD services. While data outcomes are not determinative of mental health parity compliance, the Plan uses these denial results to guide if investigations into UM processes are necessary to ensure that underlying methodology for UM procedures are applied no more stringently toward behavioral health services.</p> <p><b>Findings:</b></p>	

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
<b><i>In-Network Inpatient:</i></b>				
Total Number of In-Network Inpatient Prior Authorization Requests	16		43	
Total Number of In-Network Inpatient Prior Authorization Requests Denied	0	0%	9	21%
Total Number of In-Network Inpatient Prior Authorization Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network Inpatient Prior Authorization Requests Denied as Not Medically Necessary	0	0%	9	21%
<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of Out-of-Network Inpatient Prior Authorization Requests	2		6	
Total Number of Out-of-Network Inpatient Prior Authorization Requests Denied	0	0%	2	33%
Total Number of Out-of-Network Inpatient Prior Authorization Requests Administratively Denied	0	0%	0	0%
Total Number of Out-of-Network Inpatient Prior Authorization Requests Denied as Not Medically Necessary	0	0%	2	33%
<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
<b><i>In-Network All Other Outpatient:</i></b>				
Total Number of In-Network All Other Outpatient Prior Authorization Requests	16		296	
Total Number of In-Network All Other Outpatient Prior Authorization Requests Denied	0	0%	79	27%
Total Number of In-Network All Other Outpatient Prior Authorization Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network All Other Outpatient Prior Authorization Requests Denied as Not Medically Necessary	0	0%	76	26%
<b><i>In-Network Outpatient Office Visit:</i></b>				
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests	2		173	
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Denied	0	0%	61	35%
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Denied as Not Medically Necessary	0	0%	59	34%
<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of Out-of-Network All Other Outpatient Prior Authorization Requests	3		32	
Total Number of Out-of-Network All Other Outpatient Prior Authorization Requests Denied	0	0%	14	44%
Total Number of Out-of-Network All Other Outpatient Prior Authorization Requests Administratively Denied	0	0%	0	0%
Total Number of Out-of-Network All Other Outpatient Prior Authorization Requests Denied as Not Medically	0	0%	13	41%
<b><i>Out-of-Network Outpatient Office Visit:</i></b>				
Total Number of Out-of-Network Outpatient Office Visit Prior Authorization Requests	0		18	
Total Number of Out-of-Network Outpatient Office Visit Prior Authorization Requests Denied	0	#DIV/0!	17	94%
Total Number of Out-of-Network Outpatient Office Visit Prior Authorization Requests Administratively Denied	0	#DIV/0!	2	11%
Total Number of Out-of-Network Outpatient Office Visit Prior Authorization Requests Denied as Not	0	#DIV/0!	14	78%

**5. Provide the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.**

In-Network and	The underlying processes, strategies, evidentiary standards and other factors used to
----------------	---

<p>Out-of-Network Inpatient Services/Outpatient Services</p>	<p>apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA for the following reasons:</p> <ol style="list-style-type: none"> <li>1. The factors, sources, and evidentiary standards used to determine the methodology for assigning services to the prior authorization list is the same for MH/SUD benefits and M/S benefits.</li> <li>2. As written, the same process is employed when rendering prior authorization decisions and for assigning services to the prior authorization list across MH/SUD benefits and M/S benefits.</li> <li>3. In-operation, the Plan performs in-operation data assessments to ensure that the underlying methodology for developing the prior authorization list is applied no more stringently to MH/SUD benefits when compared to M/S benefits. Across all categories of prior authorization requests in PY 2021, there are higher denial rates for prior authorizations for M/S services when compared to MH/SUD services. The outcome measures show that prior authorization methodologies are comparable (or in this case the outcome measures are more favorable to MH/SUD benefits) because the metrics reveal more favorable outcomes for MH/SUD benefits with higher rates of approval for services overall.</li> </ol> <p><b>Findings/Conclusion:</b> The findings of the comparative analysis reveal that the process and methodology to apply prior authorization to MH/SUD benefits is comparable to, and applied no more stringently than, the process and methodology used to apply prior authorization to M/S benefits.</p>
--	--

<b>Non-Quantitative Treatment Limitation (NQTL) Analysis Index</b>	
<b>Non-Quantitative Treatment Limitation</b>	Retrospective Review
<b>Plan Type(s) Applicable</b>	Cigna + Oscar
<b>Responsible Business Teams</b>	Clinical
<b>Names of Person(s) Responsible for Analysis Formation</b>	Insiya Taj, MPH, Associate, UM Optimization, (Over 3 years experience in healthcare and clinical research) Marco Fossati-Bellani, MD, MPH, Senior Medical Director, UM
<b>Last Update</b>	7/1/2022
<b>Reviewers</b>	Alexandra Rubino, Associate Director, MHP (Over 4 years experience in Mental Health Parity reporting and operational compliance)



**Non-Quantitative Treatment Limitation (NQTL) Analysis for the Mental Health Parity and Addiction Equity Act (MHPAEA)**

**Retrospective Review**

- 1. Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply:**

<b>Medical/Surgical Terms</b>	<b>Mental Health/Substance Use Disorder Terms</b>
<p>Medical/surgical inpatient services are subject to retrospective medical necessity review if prior authorization was not obtained via the pre-service or concurrent care review process.</p> <p>Customers may request a retrospective medical necessity review. The request for retrospective review and supporting clinical information is referred to a nurse reviewer for review. If the nurse reviewer determines the customer met criteria for the services at issue, he/she authorizes the services at issue. If the nurse reviewer assesses the participant did not appear to meet medical necessity criteria for services at issue, he/she refers the case to a peer reviewer for determination.</p> <p>If the medical records support the participant met medical necessity criteria for the in-network or out-of-network services at issue, the services would be authorized. If the medical records do not support the customer met medical necessity criteria for the in-network or out-of-network services at issue, the services would be denied as not medically necessary. For denials of in-network services, participating providers are contractually obligated to hold the customer harmless for the services at issue. For denials of out-of-network services, the customer would have the right to pursue the full internal and/or external appeal process.</p>	<p>MH/SUD inpatient services are subject to retrospective medical necessity review if prior authorization was not obtained via the pre-service or concurrent care review Process.</p> <p>Customers may request a retrospective medical necessity review. The request for retrospective review and supporting clinical information is referred to appropriately licensed and credentialed clinician for review. If the clinician determines the customer met criteria for the services at issue, he/she authorizes the services at issue. If the clinician assesses the customer did not appear to meet medical necessity criteria for services at issue, he/she refers the case to a peer reviewer for determination.</p> <p>If the medical records support the participant met medical necessity criteria for the in-network or out-of-network services at issue, the services would be authorized. If the medical records do not support the customer met medical necessity criteria for the in-network or out-of-network services at issue, the services would be denied as not medically necessary. For denials of in-network services, participating providers are contractually obligated to hold the customer harmless for the services at issue. For denials of out-of-network services, the customer would have the right to pursue the full internal and/or external appeal process.</p>

Benefit Classification	Medical/Surgical Services to which the NQTL applies	Mental Health/SUD Services to which the NQTL applies
In-Network/Out-of-Network Inpatient Services	<p>All inpatient services are subject to this NQTL.</p> <ul style="list-style-type: none"> <li>• Acute/Elective Hospital</li> <li>• Hospice</li> <li>• Long-Term Acute Care</li> <li>• Rehabilitation, Acute/Subacute</li> <li>• Skilled Nursing Facility</li> </ul>	<p>All inpatient services are subject to this NQTL.</p> <ul style="list-style-type: none"> <li>• All Inpatient Admissions (Non-emergent) <ul style="list-style-type: none"> <li>○ Acute hospital</li> <li>○ Rehabilitation, Acute/Subacute</li> <li>○ Residential treatment</li> </ul> </li> </ul>
In-Network/Out-of-Network Outpatient Services	<ul style="list-style-type: none"> <li>• Physician-Administered Drugs</li> <li>• Certain DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) such as oxygen, CPAP, and diabetic supplies</li> <li>• Home Health Care Services</li> <li>• Advanced Imaging</li> <li>• Diagnostic Tests &amp; Evaluations, Laboratory Procedures</li> <li>• Outpatient Treatments/Procedures</li> <li>• Non-Emergency Transportation</li> <li>• Unlisted Procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Adaptive Behavior Assessment &amp; Therapy</li> <li>• Applied behavior analysis (ABA)</li> <li>• Detoxification programs</li> <li>• Outpatient psychiatric testing</li> <li>• Partial hospitalization treatment</li> <li>• Transcranial magnetic stimulation (TMS)</li> </ul>

**2. Identify the factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Factors Considered: Medical/Surgical	Factors Considered: Mental Health/SUD
In-Network/ Out-of-Network Inpatient Services	<ol style="list-style-type: none"> <li>1. Clinical appropriateness</li> <li>2. Safety risk</li> <li>3. Cost</li> </ol>	<ol style="list-style-type: none"> <li>1. Clinical appropriateness</li> <li>2. Safety risk</li> <li>3. Cost</li> </ol>

In-Network/ Out-of-Network Outpatient Services	<ol style="list-style-type: none"> <li>1. Cost variability</li> <li>2. Denial rate</li> <li>3. Cost percentile</li> <li>4. Safety risk</li> <li>5. New/emerging service/technology</li> <li>6. Clinical appropriateness</li> </ol>	<ol style="list-style-type: none"> <li>1. Cost variability</li> <li>2. Denial rate</li> <li>3. Cost percentile</li> <li>4. Safety risk</li> <li>5. New/emerging service/technology</li> <li>6. Clinical appropriateness</li> </ol>

**3. Identify the evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits:**

Benefit Classification	Evidentiary Standards and Sources: Medical/Surgical	Evidentiary Standards and Sources: MH/SUD
In-Network/ Out-of-Network Inpatient Services	<ol style="list-style-type: none"> <li>1. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must</li> </ol>	<ol style="list-style-type: none"> <li>1. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must</li> </ol>

	<p>be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of</li> </ul>	<p>be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>• Plan Clinical Guidelines</li> <li>• MCG</li> <li>• ASAM (SUD only)</li> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of</li> </ul>
--	---	---

	<p>Medicine;</p> <ul style="list-style-type: none"> <li>Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>Published scientific evidence;</li> <li>In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>Physical Therapy/Occupational Therapy</li> <li>Gender affirming surgeries</li> <li>Confirming member has undergone hormone therapy and counseling</li> <li>Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>Physician-administered drugs</li> <li>Level of care setting</li> </ul> <p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p> <p>2. <b>Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are</p>	<p>Medicine;</p> <ul style="list-style-type: none"> <li>Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>Published scientific evidence;</li> <li>In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>Physical Therapy/Occupational Therapy</li> <li>Gender affirming surgeries</li> <li>Confirming member has undergone hormone therapy and counseling</li> <li>Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>Physician-administered drugs</li> <li>Level of care setting</li> </ul> <p>Note: State and/or Federal regulations and guidelines take precedence over other factors, sources, and evidentiary standards.</p> <p>2. <b>Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are</p>
--	--	--

	<p>medically necessary and appropriately administered.</p> <p>Sources: National societies and health agencies, Clinical criteria<sup>1</sup>, Clinical evidence<sup>2</sup></p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at</li> </ul>	<p>medically necessary and appropriately administered.</p> <p>Sources: National societies and health agencies, Clinical criteria<sup>3</sup>, Clinical evidence<sup>4</sup></p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at</li> </ul>
--	---	---

<sup>1</sup> Clinical criteria includes: Plan Clinical Guidelines, MCG, ASAM (SUD only), Hayes, UpToDate, National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)

<sup>2</sup> Clinical evidence: The US National Library of Medicine; Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN); Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH); Published scientific evidence; In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).

<sup>3</sup> Clinical criteria includes: Plan Clinical Guidelines, MCG, ASAM (SUD only), Hayes, UpToDate, National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)

<sup>4</sup> Clinical evidence: The US National Library of Medicine; Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN); Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH); Published scientific evidence; In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).

	<p>higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</p> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf).</i></p> <p><b>3. High Cost</b></p> <p>Evidentiary Standard: The mean cost of an inpatient episode of care is &gt;\$12,000</p> <p>Source: Claims data</p>	<p>higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</p> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf).</i></p> <p><b>3. High Cost</b></p> <p>Evidentiary Standard: The mean cost of an inpatient episode of care is &gt;\$12,000</p> <p>Source: Claims data</p>
In-Network/ Out-of-Network Outpatient Services	<p><b>1. Cost variability</b> is defined as the cost per episode of service (service units X unit cost) that trigger 2x the mean of other outpatient services and provided to a minimum of twenty unique Plan members. Outpatient services are subject to variability in cost per episode of service relative to other services within the classification of benefits. For each service, the Plan calculates the Average Annual Allowed Amount per Unique Patient with Outpatient Claim Events for that Primary Service.</p> <p>Source: Claims data</p> <p>Threshold: Cost per episode of service that triggers 2x the mean of other</p>	<p><b>1. Cost variability</b> is defined as the cost per episode of service (service units X unit cost) that trigger 2x the mean of other outpatient services and provided to a minimum of twenty unique Plan members. Outpatient services are subject to variability in cost per episode of service relative to other services within the classification of benefits. For each service, the Plan calculates the Average Annual Allowed Amount per Unique Patient with Outpatient Claim Events for that Primary Service.</p> <p>Source: Claims data</p> <p>Threshold: Cost per episode of service that triggers 2x the mean of other</p>

	<p>outpatient services.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Musculoskeletal Surgery   Joint arthroscopy / arthroplasty / arthrodesis Cost variability applies to this service category. Cost variability is 5x the mean of other outpatient services.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient Psychiatric Testing Cost variability applies to this service category. Cost variability is 2.9x the mean of other outpatient services.</li> </ul> <p><b>2. Denial rate</b> is defined as the percentage of prior authorization requests that are denied by the Plan.</p> <p>Source: Prior authorization data</p> <p>Threshold: &gt;10%</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Skin Treatments &amp; Procedures   UV / Laser therapy Denial rate applies to this service category. Denial rate is 70% for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Partial Hospitalization Denial rate applies to this service category. Denial rate is 60% for</li> </ul>	<p>outpatient services.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Musculoskeletal Surgery   Joint arthroscopy / arthroplasty / arthrodesis Cost variability applies to this service category. Cost variability is 5x the mean of other outpatient services.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient Psychiatric Testing Cost variability applies to this service category. Cost variability is 2.9x the mean of other outpatient services.</li> </ul> <p><b>2. Denial rate</b> is defined as the percentage of prior authorization requests that are denied by the Plan.</p> <p>Source: Prior authorization data</p> <p>Threshold: &gt;10%</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Skin Treatments &amp; Procedures   UV / Laser therapy Denial rate applies to this service category. Denial rate is 70% for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Partial Hospitalization Denial rate applies to this service category. Denial rate is 60% for</li> </ul>
--	---	---

	<p>this service category.</p> <p><b>3. Cost percentile</b> is defined as the average cost per claim event for a particular outpatient service relative to other services within the classification of benefits.</p> <p>Source: Claims data</p> <p>Threshold: <math>\geq</math> 85th Percentile</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Digestive Treatments &amp; Procedures   Bariatric surgery Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient psychiatric testing Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> </ul> <p><b>4. Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health</p>	<p>this service category.</p> <p><b>3. Cost percentile</b> is defined as the average cost per claim event for a particular outpatient service relative to other services within the classification of benefits.</p> <p>Source: Claims data</p> <p>Threshold: <math>\geq</math> 85th Percentile</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>Benefit: Medical/Surgical Service: Outpatient Services: Treatments &amp; Procedures: Digestive Treatments &amp; Procedures   Bariatric surgery Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> <li>Benefit: Mental Health/Substance Use Disorder Service: Outpatient psychiatric testing Cost percentile applies to this service category. Cost is in the 100th percentile for this service category.</li> </ul> <p><b>4. Safety risk</b> is defined as healthcare services that have the potential to harm patients and increase the risk of adverse events. The prior authorization process helps alleviate safety risks and protects patient health by ensuring that procedures, treatments, surgeries, and prescribed medications are medically necessary and appropriately administered.</p> <p>Sources: National societies and health</p>
--	--	--

	<p>agencies, Clinical criteria, Clinical evidence</p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf).</i></p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>Plan Clinical Guidelines</li> <li>MCG</li> <li>ASAM (SUD only)</li> </ul>	<p>agencies, Clinical criteria, Clinical evidence</p> <ul style="list-style-type: none"> <li>Centers for Medicare &amp; Medicaid Services</li> <li>World Health Organization</li> <li>Institute For Safe Medication Practices</li> <li>U.S. Food and Drug Administration</li> <li>Drug labeling / safety information</li> </ul> <p>Evidentiary Standards:</p> <ul style="list-style-type: none"> <li>Treatments that increase the likelihood of adverse health effects</li> <li>Services that increase the likelihood of perioperative morbidity and mortality</li> <li>Procedures, such as high-risk operations, that carry a mortality rate of 5% or more.</li> <li>Procedures with significant or major impact on hemodynamics, fluid shifts, possible major blood loss.</li> <li>Drugs (including those dosed at higher than standard doses) that may have adverse health effects, possibly dangerous interactions, medication errors, and/or risks for abuse or misuse.</li> </ul> <p><i>Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (http://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf).</i></p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>Plan Clinical Guidelines</li> <li>MCG</li> <li>ASAM (SUD only)</li> </ul>
--	--	--

	<ul style="list-style-type: none"> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Surgical procedures at risk for infection and complications (e.g., gastrectomy, hip replacement)</li> <li>• Advanced radiology procedures with exposure to radiation (e.g., CT, MRI, nuclear medicine)</li> <li>• Physician-administered drugs due to the risk for adverse effects and contraindications (e.g., chemotherapeutic agents)</li> </ul> <p><b>5. New/ Emerging Service/ Technology</b> is defined as any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven.</p>	<ul style="list-style-type: none"> <li>• Hayes</li> <li>• UpToDate</li> <li>• National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>• The US National Library of Medicine;</li> <li>• Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>• Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>• Published scientific evidence;</li> <li>• In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Surgical procedures at risk for infection and complications (e.g., gastrectomy, hip replacement)</li> <li>• Advanced radiology procedures with exposure to radiation (e.g., CT, MRI, nuclear medicine)</li> <li>• Physician-administered drugs due to the risk for adverse effects and contraindications (e.g., chemotherapeutic agents)</li> </ul> <p><b>5. New/ Emerging Service/ Technology</b> is defined as any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven.</p>
--	---	---

	<p>Services that are not accepted as the standard medical treatment of the condition being treated are considered “new and emerging services and technologies.” This includes any health care service, testing, procedure, treatment, device, or prescription drug that:</p> <ul style="list-style-type: none"> <li>• Is not accepted as standard medical treatment of the condition; or</li> <li>• Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; or</li> <li>• Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or</li> <li>• Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; or</li> <li>• Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p>	<p>Services that are not accepted as the standard medical treatment of the condition being treated are considered “new and emerging services and technologies.” This includes any health care service, testing, procedure, treatment, device, or prescription drug that:</p> <ul style="list-style-type: none"> <li>• Is not accepted as standard medical treatment of the condition; or</li> <li>• Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; or</li> <li>• Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or</li> <li>• Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; or</li> <li>• Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p>
--	---	---

	<p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>● The US National Library of Medicine;</li> <li>● Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>● Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>● Published scientific evidence;</li> <li>● In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>● Genetic, biomarker and molecular tests</li> <li>● Medical devices and implants</li> <li>● Novel therapies (e.g., gene therapy, CAR T-Cell therapy)</li> </ul> <p>6. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based</p>	<p>Evidentiary Standards:</p> <p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>● The US National Library of Medicine;</li> <li>● Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>● Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>● Published scientific evidence;</li> <li>● In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>● Genetic, biomarker and molecular tests</li> <li>● Medical devices and implants</li> <li>● Novel therapies (e.g., gene therapy, CAR T-Cell therapy)</li> </ul> <p>6. <b>Clinical appropriateness</b> is defined as services with a narrow appropriateness of indication as per evidence-based guidelines clearly defined by specialty societies and/or governing bodies. Clinical appropriateness is applicable when evidence-based</p>
--	--	--

	<p>criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p>	<p>criteria is required to confirm the service is (a) medically necessary, (b) delivered in the appropriate setting or level of care, and (c) substantiated by nationally recognized guidelines to be safe and effective for the member's illness, injury, or disease, taking into account factors such as treatment type, frequency, extent, site, and duration. Services must be provided by licensed practitioners (e.g., DNP, DO, MD, PA) in accordance with evidence-based practice.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• As per World Professional Association for Transgender Health (WPATH) guidelines, prior authorization review of sex reassignment (gender affirmation) surgery confirms a persistent diagnosis with gender dysphoria WPATH guidelines.</li> <li>• As per the American Psychological Association (APA), Applied Behavior Analysis is appropriate for children with autism spectrum disorder.</li> <li>• As per the National Comprehensive Cancer Network (NCCN), radiation and chemotherapy requires confirmation of certain types of cancer and individualized needs as documented in the medical record.</li> </ul> <p>Sources: Clinical criteria, Clinical evidence</p> <p>Evidentiary Standards:</p>
--	---	---

	<p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>● The US National Library of Medicine;</li> <li>● Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>● Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>● Published scientific evidence;</li> <li>● In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>● Physical Therapy/Occupational Therapy</li> <li>● Gender affirming surgeries</li> <li>● Confirming member has undergone hormone therapy and counseling</li> <li>● Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>● Physician-administered drugs</li> <li>● Level of care setting</li> </ul>	<p>Clinical criteria</p> <ul style="list-style-type: none"> <li>● Plan Clinical Guidelines</li> <li>● MCG</li> <li>● ASAM (SUD only)</li> <li>● Hayes</li> <li>● UpToDate</li> <li>● National Society Guidelines (e.g., ACOG, APA, NCCN, WPATH)</li> </ul> <p>Clinical evidence</p> <ul style="list-style-type: none"> <li>● The US National Library of Medicine;</li> <li>● Guidelines and publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., ACOG, IDSA, NCCN);</li> <li>● Guidance or regulatory status published by Government Regulatory Agencies (e.g., CDC, CMS, FDA, NIH);</li> <li>● Published scientific evidence;</li> <li>● In consultation with medical experts and providers who have expertise in the particular area of the services (e.g., board-certified physician specialists).</li> </ul> <p>Examples:</p> <ul style="list-style-type: none"> <li>● Physical Therapy/Occupational Therapy</li> <li>● Gender affirming surgeries</li> <li>● Confirming member has undergone hormone therapy and counseling</li> <li>● Mastectomy - appropriate in most cases, but need to review for medical necessity</li> <li>● Physician-administered drugs</li> <li>● Level of care setting</li> </ul>
	Note: State and/or Federal regulations and guidelines take precedence over	Note: State and/or Federal regulations and guidelines take precedence over

	other factors, sources, and evidentiary standards.	other factors, sources, and evidentiary standards.
--	--	--

**4. Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and**

*For each MH/SUD and M/S benefit subject to Retrospective Review, identify which of the factor(s) in Step 3 were met:*

**In-Network/Out-of-Network Outpatient M/S**

Service	Cost variability	Denial rate	Cost percentile	Safety risk	New/ Emerging Service/ Technology	Clinical Appropriateness
Physician-Administered Drugs		X		X	X	X
DMEPOS		X	X		X	X
Home Health Care Services		X				X
Advanced Imaging		X		X		
Diagnostic Tests & Evaluations, Laboratory Procedures		X	X		X	X
Treatments/ Procedures	X	X	X	X	X	X
Non-Emergency		X	X			

Transportation						
Unlisted Procedures	<b>X</b>	<b>X</b>		<b>X</b>	<b>X</b>	

### In-Network/Out-of-Network Outpatient MH/SUD

Service	Cost variability	Denial rate	Cost percentile	Safety risk	New/ Emerging Service/ Technology	Clinical Appropriateness
Adaptive Behavior Assessment & Therapy	<b>X</b>					<b>X</b>
Applied behavior analysis (ABA)	<b>X</b>					<b>X</b>
Detoxification programs	<b>X</b>		<b>X</b>			
Outpatient psychiatric testing	<b>X</b>	<b>X</b>	<b>X</b>			
Partial hospitalization treatment	<b>X</b>	<b>X</b>				<b>X</b>
Transcranial magnetic stimulation (TMS)	<b>X</b>					<b>X</b>

Retrospective Review Process M/S	Retrospective Review Process MH/SUD
<p>A retrospective review is conducted when the Plan receives a request for coverage of medical care or services that have already been received, or when prior authorization was required but not obtained and a claim was submitted for the service. A written notification is issued to the member and provider within state, federal, or</p>	

accreditation required timeframes; the written notification includes information on appeal rights. The Plan follows all state, federal, and accreditation timeframe requirements. After an adverse determination has been issued, the Plan offers the opportunity for the provider to discuss the request with a Plan physician. This peer to peer discussion is not considered part of a grievance or appeal process.

The Plan requires the requesting provider to submit the following information when requesting an authorization:

- Member information (name, Plan ID, date of birth).
- Facility (if applicable).
- referring and treating provider name, National Provider Identifier (NPI), and Taxpayer Identification Number (TIN).
- Treatment information including diagnostic and/or procedure codes, requested amount and length of treatment(s).

Both the providers and members are notified of the determination consistent with state, federal and accreditation requirements and applicable appeal rights are provided.

***For each committee used to determine which benefits to subject to Retrospective Review, describe the committee's purpose, composition and member qualifications, and process:***

Committee Information M/S	Committee Information MH/SUD
<p>The OMC Board of Directors has the ultimate authority and responsibility for the quality of care and services delivered to its members. The Board of Directors provides strategic planning and direction, budget approval, and staff allocation for the UM Department. The Board of Directors assigns day-to-day responsibility for implementation of the UM Program to the UM Subcommittee, which is a subcommittee of the Quality Improvement Committee. The Board of Directors oversees the implementation of and adherence to the UM Program through the UM Subcommittee. The UM Subcommittee reports to the Quality Improvement Committee at a minimum of once per quarter, per year. The UM Program and Annual Program Evaluation are approved at the UM Subcommittee portion of the Quality Improvement Committee meeting. Minutes conveying this approval are submitted to the Board of Directors, who approve the actions of the Quality Improvement Committee. The Board of Directors delegates the responsibility for the oversight and operations of the UM Program to the Chief Medical Director (CMO). The CMO oversees the UM Program with input from the Quality Improvement Committee, and support from members of the UM staff (clinical and non-clinical).</p> <p>As noted above, the UM Subcommittee is a sub-committee to the Quality Improvement Committee. A senior-level physician chairs the UM Subcommittee with representation from licensed physicians (MD, DO) and licensed nurses (RN). Key health plan functions are represented at the meeting, including participation of the behavioral health designated physician (MD, clinical PhD, PsyD). Additional internal department</p>	

representatives attend based on identified needs. The UM Subcommittee meets quarterly, or more frequently as necessary.

The UM Subcommittee undertakes, but is not limited to, the following ongoing activities:

- Evaluates and refines the UM Program through analysis of curated objective metrics and subjective feedback from members and Providers, making recommendations for intervention when indicated.
- Reviews and approves modifications to the UM Program as indicated by operational needs and/or to meet regulatory and accreditation compliance.
- Reviews and approves written Clinical Criteria and protocols for the determination of medical necessity and appropriateness of healthcare procedures and services.
- Reviews and approves modifications to the healthcare procedures and services subject to Prior Authorization.

*Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization*

Benefit Classification	Process Description: Medical/Surgical	Process Description: MH/SUD
In-Network Inpatient Services/Outpatient Services	<p>The Plan ensures that processes, strategies, and evidentiary standards used in applying retrospective review is comparable and no more stringently applied to mental health/substance use disorder (MH/SUD) benefits and medical/surgical (M/S) benefits, both as written and in operation. This includes the retrospective review request process and factors, sources, and evidentiary standards that contribute to the development of the retrospective review list.</p> <p>The factors, sources, evidentiary standards, and process for retrospective review decisions are the same across M/S and MH/SUD benefits. For both MH/SUD benefits and M/S benefits, medical necessity review is conducted by licensed clinicians, and medical necessity determinations are based on whether the treatment/services are consistent with the member's coverage, medically appropriate, and consistent with evidence-based practice. Retrospective review processes for M/S benefits and MH/SUD benefits follow state, federal, or accreditation timeframe requirements. Therefore, as-written, retrospective review is applied no more stringently to MH/SUD benefits when compared to M/S benefits.</p> <p>Operationally, the Plan performs in-operation data assessments to ensure that factors, sources, and evidentiary standards are applied in a consistent manner across benefits. For UM, the Plan reviews rates of denials for retrospective review across benefit categories and compares these denial rates for M/S services against MH/SUD services. While data outcomes are not determinative of mental health parity compliance, the Plan uses these denial results to guide if investigations into UM processes are necessary to ensure that underlying methodology for UM procedures are applied no more stringently toward behavioral health services.</p>	

## Findings:

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of In-Network Inpatient Retrospective Reviews Requests	3		55	
Total Number of In-Network Inpatient Retrospective Review Denials	0	0%	13	24%
Total Number of In-Network Inpatient Retrospective Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network Inpatient Retrospective Requests Denied as Not Medically Necessary	0	0%	13	24%

  

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of Out-of-Network Inpatient Retrospective Reviews Requests	0		4	
Total Number of Out-of-Network Inpatient Retrospective Review Denials	0	#DIV/0!	2	50%
Total Number of Out-of-Network Inpatient Retrospective Requests Administratively Denied	0	#DIV/0!	0	0%
Total Number of Out-of-Network Inpatient Retrospective Requests Denied as Not Medically Necessary	0	#DIV/0!	2	50%

  

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of In-Network All Other Outpatient Retrospective Reviews Requests	1		25	
Total Number of In-Network All Other Outpatient Retrospective Review Denials	0	0%	9	36%
Total Number of In-Network All Other Outpatient Retrospective Requests Administratively Denied	0	0%	0	0%
Total Number of In-Network All Other Outpatient Retrospective Requests Denied as Not Medically Necessary	0	0%	9	36%

  

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of In-Network Outpatient Office Visit Reviews Requests	0		2	
Total Number of In-Network Outpatient Office Visit Retrospective Review Denials	0	#DIV/0!	1	50%
Total Number of In-Network Outpatient Office Visit Retrospective Requests Administratively Denied	0	#DIV/0!	0	0%
Total Number of In-Network Outpatient Office Visit Retrospective Requests Denied as Not Medically Necessary	0	#DIV/0!	1	50%

  

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of Out-of-Network All Other Outpatient Retrospective Reviews Requests	0		4	
Total Number of Out-of-Network All Other Outpatient Retrospective Review Denials	0	#DIV/0!	2	50%
Total Number of Out-of-Network All Other Outpatient Retrospective Requests Administratively Denied	0	#DIV/0!	0	0%
Total Number of Out-of-Network All Other Outpatient Retrospective Requests Denied as Not Medically Necessary	0	#DIV/0!	2	50%

  

<b>I. Utilization Reviews Requests and Denied:</b>	<b>MH/SUD</b>	<b>MH/SUD Denial Rate</b>	<b>Med-Surg. (M/S)</b>	<b>M/S Denial Rate</b>
Total Number of Out-of-Network Outpatient Office Visit Retrospective Reviews Requests	0		0	
Total Number of Out-of-Network Outpatient Office Visit Retrospective Review Denials	0	#DIV/0!	0	#DIV/0!
Total Number Out-of-Network Outpatient Office Visit Retrospective Requests Administratively Denied	0	#DIV/0!	0	#DIV/0!
Total Number of Out-of-Network Outpatient Office Visit Retrospective Requests Denied as Not Medically Necessary	0	#DIV/0!	0	#DIV/0!

**5. Provide the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.**

In-Network and Out-of-Network Inpatient	The underlying processes, strategies, evidentiary standards and other factors used to apply the NQTL to MH/SUD benefits and to M/S benefits have led the Plan to conclude compliance with MHPAEA for the following reasons:
---	---

<p>Services/Outpatient Services</p>	<ol style="list-style-type: none"> <li>1. The factors, sources, and evidentiary standards used to determine the methodology for assigning services to the retrospective review list is the same for MH/SUD benefits and M/S benefits.</li> <li>2. As written, the same process is employed when rendering retrospective review decisions and for assigning services to the retrospective review list across MH/SUD benefits and M/S benefits.</li> <li>3. In-operation, the Plan performs in-operation data assessments to ensure that the underlying methodology for developing the retrospective review list is applied no more stringently to mental health/substance use disorder services when compared to medical/surgical services. Across all categories of retrospective review requests in PY 2021, there are higher denial rates for retrospective review for M/S services when compared to MH/SUD services. The outcome measures show that retrospective review methodologies are comparable because the metrics reveal more favorable outcomes for MH/SUD benefits with higher rates of approval for services overall.</li> </ol> <p><b>Findings/Conclusion:</b> The findings of the comparative analysis reveal that the process and methodology to apply retrospective review to MH/SUD services is comparable to, and applied no more stringently than, the process and methodology used to apply retrospective review to M/S services.</p>
-------------------------------------	---