Section (Primary Department) **Health Care Management - Utilization Management**		**SUBJECT (Document Title)** **Health Care Management Denial - LA**	
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Department Approval/Signature:			

Policy applies to health plans operating in the following State(s). Applicable products noted below.

Products				
☒ **Medicaid/CHIP**	☐ Arkansas	☐ Iowa	☐ Nevada	☐ Tennessee
☐ **Medicare/SNP**	☐ California	☐ Kentucky	☐ New Jersey	☐ Texas
☐ **MMP/Duals**	☐ Colorado	☒ Louisiana	☐ New York – Empire	☐ Virginia
	☐ District of Columbia	☐ Maryland	☐ New York (WNY)	☐ Washington
	☐ Florida	☐ Minnesota	☐ North Carolina	☐ West Virginia
	☐ Georgia	☐ Missouri	☐ Ohio	☐ Wisconsin
	☐ Indiana	☐ Nebraska	☐ South Carolina	

POLICY:

To ensure timely utilization decisions which accommodate the clinical urgency and necessity of a situation.

Healthy Blue makes adverse benefit determinations only as provided for in its contractual agreement and in accordance with state and federal law and regulation. Upon making such determinations, Healthy Blue provides all notices and opportunities for grievance and appeals required contractually or by state and federal law or regulation.

Healthy Blue ensures members receive notices of adverse benefit determinations per 42 CFR 438.915(b) and other requirements which extend notice requirements beyond denials. All determination of action notices must be in writing and meet the language and format requirements of the Contract and 42 CFR §438.10 to ensure ease of understanding. All action notices are completed in compliance with the Balanced Budget Act (BBA), National Committee for Quality Assurance (NCQA), and contractual guidelines.

Healthy Blue is responsible for eliciting pertinent health record information from the treating health care provider(s), as needed and/or as requested by LDH, for purposes of making Service Authorization determinations. Healthy Blue shall take appropriate action when a treating health care provider does not provide complete medical history information within the requested timeframe.

Healthy Blue shall ensure that Service Authorization criteria are consistent with applicable Federal and State laws, regulations, rules, policies, procedures, and manuals, the State Plan, and Waivers. Healthy Blue shall only use criteria that:

- Are adopted in consultation with contracted healthcare providers
- Are objective and based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field

- Consider the needs of the Enrollees; and
- Are updated periodically as appropriate

Healthy Blue shall clearly identify the source of the criteria and include:

- The vendor if the criteria were purchased;
- The association if the criteria are developed/recommended or endorsed by a national or state health care provider association or society; and/or
- The guideline source if the criteria are based on a published clinical practice guideline

Service Authorization Staffing Requirements:

- Healthy Blue shall ensure that compensation to individuals or entities that conduct UM activities is not structured to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary MCO covered services to any member in accordance with 42 CFR §438.3(i) and 42 CFR §422.208.
- Healthy Blue shall ensure that only licensed clinical professionals with appropriate clinical expertise in the treatment of an Enrollee's condition or disease and training in the use of any required assessments shall determine Service Authorization request denials or authorize a service in an amount, duration or scope that is less than requested.
    - The individual making determinations shall attest that no adverse determination will be made regarding any medical procedure or service outside of the scope of the individual's expertise
- Healthy Blue shall ensure that staff consistently and correctly apply authorization criteria and make appropriate determinations, including a process to ensure staff performing below acceptable thresholds on inter-rater reliability tests are not permitted to make independent authorization determinations until such time that the staff member can be retrained, monitored, and demonstrate performance that meets or exceeds the acceptable threshold
- The individual(s) making determinations shall have no history of disciplinary action or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical peer reviewer's physical, mental, or professional or moral character.
- Healthy Blue shall provide staff specifically assigned to SBHS and PSH to ensure appropriate authorization of tenancy services

DEFINITIONS:

** Denotes terms for which Healthy Blue must use the State-developed definition.*

Administrative Denial – The denial of a requested service or confinement for reasons that are unrelated to medical necessity, such as late notification of an admission, failure to precertify a service that requires precertification, or ineligibility on date of service, that does not require review by a Medical Director or appropriate practitioner.

Adverse Action – Any decision by Healthy Blue to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested.

Adverse Benefit Determination – Means any of the following:

- The denial or limited authorization of a requested service, including, but not limited ~~determinations~~to, determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.
- The reduction, suspension, or termination of a previously authorized service.
- The denial, in whole or in part, of payment for a service. ~~A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a "clean claim" in accordance with 42 CFR §447.45(b) is not an adverse benefit determination.~~
- The failure to provide services in a timely manner, as defined by the State.
- The failure of Healthy Blue to act within the timeframes provided in 42 CFR §438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals.
- The denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities.

Appeal Procedure – A formal process whereby an enrollee can ~~request review or~~ contest an adverse determination rendered by Healthy Blue, which resulted in the denial, reduction, suspension, termination or delay of health care benefits/services. The appeal procedure shall be governed by federal and state laws, ~~and~~ regulations, rules, policies, and manuals, and all applicable court orders and consent decrees.

Informal Reconsideration – Appeal process that allows the member (or provider/agent on behalf of a member) a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. This can occur anytime during the review process. A peer-to-peer allows the member/provider the opportunity to discuss a medical necessity denial decision with the Medical Director or appropriate practitioner.

Medical Denial – An admission, continued stay, availability of care, or other healthcare service that has been reviewed by Healthy Blue and based upon the clinical information provided, does not meet the requirements for medical necessity, level of care, healthcare setting, appropriateness, or effectiveness, and the requested service is therefore denied, reduced, suspended, delayed, or terminated.

Medically Necessary Services* – Those health care services that are in accordance with generally accepted, evidence-based medical standards or that are considered by most physicians (or other independent licensed practitioners) within the community of their respective professional organizations to be the standard of care. In order to be considered medically necessary, services must be: (1) deemed reasonably necessary to diagnose, correct, cure, alleviate or prevent the worsening of a condition or conditions that endanger life, cause suffering or pain or have resulted or will result in a handicap, physical deformity or malfunction; and (2) those for which no equally effective, more conservative and less costly course of treatment is available or suitable for the beneficiary. Any such services must be individualized, specific and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and neither more nor less than what the beneficiary requires at that specific point in time. Although a service may be deemed medically necessary, it doesn't mean the service will be covered under the Medicaid Program. Services that are experimental, non-FDA approved, investigational, or cosmetic are specifically excluded from Medicaid coverage and will be deemed "not medically necessary."

Not Liable Denial – An administrative denial of a request for services based on a lack of the health plan liability for the requested services (e.g., the member is no longer eligible for services through the health plan). There are certain instances where the Medical Director (or appropriate practitioner) is required to review and render a determination for not liable reasons.

Notice of Action – Communication of a proposed action.

Provider Preventable Condition (PPC)/Health Care Acquired Condition (HCAC) – Preventable healthcare-acquired or other provider-preventable conditions and events, also known as never events, identified by the Louisiana Department of Health (LDH) for nonpayment, such as but not limited to, bed pressure ulcers or decubitus ulcers; or events such as surgical or invasive procedures performed on the wrong body part or wrong patient; wrong surgical procedure performed on a patient.

~~**Qualified Practitioner* –** An appropriately qualified practitioner who makes utilization management medical necessity denial determinations. Depending on the type of case, the qualified reviewer may be a health plan Medical Director, or a physician, pharmacist, chiropractor, clinical psychologist, dentist, nurse practitioner, physical therapist, or other licensed and qualified practitioner type as appropriate. Licensed health care professionals will include appropriately qualified practitioners in accordance with state laws.~~

- ~~The qualifications of staff who determine medical necessity are identified. The individuals who make medical necessity determinations must be identified if the criteria are based on the medical training, qualifications, and experience of the Medical Director or other qualified and trained professionals.~~

- ~~Determinations of medical necessity must be made by qualified and trained practitioners in accordance with state and federal regulations.~~
- ~~Healthy Blue ensures that only licensed clinical professionals with appropriate clinical expertise in the treatment of a member's condition or disease determine service authorization request denials or authorize a service in an amount, duration or scope that is less than requested.~~
- ~~The individual(s) making these determinations shall have no history of disciplinary action or sanctions; including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical peer reviewer's physical, mental, or professional or moral character.~~
- ~~The individual making these determinations is required to attest that no adverse determination will be made regarding any medical procedure or service outside of the scope of such individual's expertise.~~
- ~~Compensation to individuals or entities that conduct utilization management activities is not structured to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary covered services to any member in accordance with 42 CFR §438. 3 (i) and 42 CFR §422.208.~~

Service Authorization – A utilization management activity that includes pre-, ~~prospective,~~ concurrent, or post-review of a service by a qualified health professional to authorize, partially deny, or deny the payment of a service, including a service requested by the enrollee. Service authorization activities must consistently apply review criteria.

PROCEDURE:

Medical Necessity Review

Medical necessity review requires that denial decisions be made by an appropriate clinical professional as specified in NCQA standards. Denials resulting from medical necessity review are within NCQA scope of review.

Decisions about the following **require** medical necessity review:

1) Covered medical benefits defined by the organization's Certificate of Coverage or Summary of Benefits.
2) Preexisting conditions, when ~~the member has creditable coverage and~~ the organization has a policy to deny ~~preexisting care or services.~~ coverage or care for services related to pre-existing conditions.
3) Care or services whose coverage depends on specific circumstances.
4) Dental surgical procedures that occur within or adjacent to the oral cavity or sinuses and are covered under the member's medical benefits.

5) Out-of-network services that are only covered in clinically appropriate situations.
6) Prior authorizations for pharmaceuticals and pharmaceutical requests requiring prerequisite drug for a step therapy program.
7) "Experimental" or "investigational" requests, unless the requested services or procedures are specifically excluded from the benefits plan and deemed never medically necessary under any circumstance in the organization's policies, medical necessity review is not required.

Decisions about the following **do not require** medical necessity review:
1) Services in the member's benefits plan that are limited by number, duration or frequency.
2) Extension of treatments beyond the specific limitations and restrictions imposed by the member's benefits plan.
3) Care or services whose coverage ~~that~~ does not depend on any circumstances.

Requests for coverage of out-of-network services that are only covered when medically necessary or in clinically appropriate situations require medical necessity review. Such requests indicate the member has a specific clinical need that the requestor believes cannot be met in-network (e.g., a service or procedure not provided in-network; delivery of services closer or sooner than provided or allowed by the organization's access or availability standards).

If the certificate of coverage or summary of benefits specifies that the organization never covers an out-of-network service for any reason or if the request does not indicate the member has a specific clinical need for which out-of-network coverage may be warranted, the request does not require medical necessity review.

Medical Denial

1) It is the provider's responsibility to submit all clinical information necessary to justify both severity of illness and intensity of service. If the clinical submitted is inadequate, Healthy Blue may deny the request or request additional information.
2) Documented efforts are made to obtain the necessary information to provide additional support for decisions based on established medical necessity criteria. When Healthy Blue requests additional information, the turnaround time clock for concurrent review does not start until all necessary clinical information to make the decision to approve or deny initial or continued inpatient stay is received.
3) When submitting additional documentation, providers should only submit the pertinent clinical information needed to justify severity of illness and intensity of service.
4) In cases where the provider or member will not release necessary information, Healthy Blue may deny authorization of requested services within two (2) business days.

5) In the event there is insufficient information to render an approval, the request is forwarded to the Medical Director (or appropriate practitioner) for final medical necessity determination.
6) The Medical Director (or appropriate practitioner) is available to make decisions as needed and in urgent cases, as required by the medical situation.
   a) The determination and rationale of the Medical Director (or appropriate practitioner) is documented, the appropriate denial code is entered in the medical management system, and the notice of proposed action is generated.

Any medical necessity decision (medical or behavioral health) to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, must be made by a licensed physician (or appropriate practitioner) as appropriate to the scope of their expertise and training, consistent with the Contract and state and federal regulations.

1) Ensuring appropriate clinical expertise:
   ~~a) Physical Health UM reviewers label all cases as adult (twenty-two (22) years of age and older) or pediatric (birth through twenty-one (21) years of age) before pending to the Medical Director (MD) for review.~~
   ~~b) Adult and pediatric queues will be available in the medical management system, Anthem Care Management Platform (ACMP).~~
   ~~c)~~a) Designated physicians with adult clinical expertise (e.g., Internal Medicine, Emergency Medicine or Family Practice) review adult requests for services and designated physicians with pediatric clinical expertise (e.g., Pediatrician, Emergency Medicine or Family Practice) review pediatric requests for services.
   ~~d)~~b) When the pediatric MD completes all available pediatric reviews, he/she assists by reviewing adult cases, which require attestation by an appropriate and qualified adult MD.
      i) The pediatric MD notifies (via the Louisiana Medical Director Microsoft Teams) a physician on the Louisiana Physician Roster with clinical expertise in Family Practice, Emergency or Internal Medicine to attest to the adult cases he/she has reviewed.
      ii) The cases needing attestation are labeled “MDR Approval/Denial Needing Attestation.”
      iii) The adult MD attestation note is labeled “MDR Attestation.”
      iv) The attesting MD reviews the case and uses the following attestation statement if he/she agrees: “This is to attest that I have reviewed the clinical information submitted for this episode of care in its entirety, and the recommendation completed by Dr. (Name), (Credentials) on (Date), and agree with the denial determination and rationale based upon the health plan’s guideline cited. I attest that I have the clinical expertise to review this medical procedure/service.”

v) The attesting physician appropriately routes the attested case based on service type (i.e., concurrent or precertification) and determination (i.e., approval or denial).
vi) If the attesting MD does not agree, a denial note with rationale must be completed and routed to the appropriate denial queue.
vii) This process continues until the delegated adult MD notifies the Louisiana Physician Team that the MDR queues are cleared and completed for the day.

2) Ensuring appropriate clinical expertise during the peer-to-peer process:
   a) Peer-to-peers require the physician performing the peer-to-peer have clinical expertise with children (i.e., Pediatrician, Emergency Medicine or Family Practice) for members under the age of twenty-two (22); members age twenty-two (22) and over require Internal Medicine, Emergency Medicine or Family Practice expertise.
   b) The physician performing the initial adverse determination or attesting to the adverse determination will complete the peer-to-peer. If that individual is not available, a designated clinical peer physician meeting the age requirement expertise above will complete the peer-to-peer.
3) Healthy Blue ensures only licensed clinical professionals with appropriate clinical expertise in the treatment of a~~n~~ member's condition or disease and training in the use of any required assessments shall determine Service Authorization request denials or authorize a service in an amount, duration or scope that is less than requested. Ensuring adverse determinations are made within the reviewing Medical Director/Clinician's scope of clinical expertise:
   a) When a Medical Director reviews a request for services, she/he will determine if the medical procedure/services is within their clinical scope of expertise to review for medical necessity.
   b) If the procedure/service is within their scope to review for medical necessity, he/she shall attest as follows: "I attest that I have the clinical expertise to review this medical procedure/service."
   c) If the procedure/service is outside of their scope to review for medical necessity, she/he will identify a physician from the Louisiana or Corporate ~~Anthem~~ Physician Roster that has the clinical expertise and will consult with that physician or seek approval for that physician to complete the medical necessity review.
   d) Consultations shall be documented in the clinical note.

NOTE: In the event a preservice request is identified as appropriate for a lower level of care (i.e., elective inpatient admission appropriate for outpatient) and the member has not yet received the service, the health plan clinician discusses the most appropriate level of care with the provider/facility clinician. ~~If the provider/facility is in agreement with the decision, all the applicable information is documented and the medical management system is updated to reflect the appropriate, agreed upon lower level of care~~. This does ~~not~~ constitute a denial, but

the provider/facility has the option to submit a formal request for the services to be performed in a lower level of care. ~~and a noticed of proposed action is not required.~~

Administrative Denial

1) **Late Notification of an Admission** (not applicable to Emergency Services during post stabilization care):
   ~~1)~~ Notification of admission is the essential first step for the provider in the authorization process. It is important to remember that the notification step is separate from the submission of clinical for review. Providers should only submit notification and clinical information to the number(s) specified by Healthy Blue. Providers are required to notify the UM Medicaid Prior Auth team or Clinical Behavioral Health (BH) staff within twenty-four (24) hours, or one (1) business day, of an inpatient admission.
   a) Late notification is issued when Healthy Blue is notified of an emergent inpatient admission greater than one (1) business day after the admission or actual date of service:
      i) Emergency room (ER)/direct admit to a general floor (i.e., medical surgical bed);
      ~~i)~~ii) OB delivery
      ~~ii)~~iii) Neonatal intensive care unit (NICU) level I and II;
      ~~iii)~~iv) Inpatient transfers between acute, rehabilitative, long-term acute care (LTAC), or skilled nursing facilities (SNF);
      ~~iv)~~v) Inpatient transfer to a general bed from an intensive care unit (ICU)/telemetry/NICU III or post-surgery;
      ~~v) Notification greater than ten (10) days after a member admitted regardless of status;~~
      vi) Notification occurred after a member discharged home; and
      vii) Outpatient procedures listed as "notification."
   b) If the member is still inpatient when a late notification is received, the days prior to notification are administratively denied and medical necessity criteria is applied for the remaining days.
   c) If Healthy Blue was not notified of the admission and the member has been discharged, the entire stay is administratively denied for non-notification.
      i) **NOTE:** In some cases, notification and/or initial clinical is sent on the day of discharge or after discharge. These cases do not fall into the concurrent review category, but fall into the retrospective or post-service authorization category as the service has already been provided and Healthy Blue has no ability to impact the stay.
   d) The late notification denial reason is also utilized for late clinical submissions.
      i) Healthy Blue is held accountable by LDH to meet turnaround time deadlines, and therefore has the authority to implement and require adequate processing time for submitted clinical information by providers. Providers submitting clinical

information for concurrent review or as otherwise directed, have a submission deadline of 3:00 pm Central Time (CT), with a ten (10) minute grace period.

ii) It is the provider's responsibility to submit clinical information for review by the specified "Next Review" date and deadline of 3:10 pm CT.

iii) If the "Next Review" date notification sent by Healthy Blue to the provider is a past date, retrospective, or the same day of receipt, the provider has until 3:10 pm CT on the next business day to submit clinical information.

iv) Receipt of administrative denial is based on timely notification, not medical necessity. Upon receipt of this denial, providers have until 3:10 pm CT the next business day to submit clinical information for the days following the denied day to be considered for medical necessity and minimize additional denied days.

e) Proof of a fax confirmation for transmittal prior to the specified time will be accepted as meeting the deadline. If documentation was not submitted within the required timeframe, the admission or length of stay extension will be denied.

f) Prior to the issuance of a late notification denial, approval is obtained from the Utilization Management manager or his/her designee.

g) The determination rationale and appropriate denial code are entered in the medical management system and the notice of proposed action is generated.

2) **Failure to Precertify:** Precertification requests are required to be submitted a minimum of seventy-two (72) hours before services are rendered. Requests made less than this timeframe may result in an administrative denial;

a) Failure to precertify is issued for preservice requests less than seventy-two (72) hours in advance of the requested service:

i) Elective admission to an acute inpatient facility;

~~ii) Admission to inpatient hospice; or~~

~~iii)~~ii) Admission to a SNF, LTAC, or a rehabilitative facility.

b) If notification was received after an elective inpatient admission but the member is still inpatient, the days prior to the notification are administratively denied and medical necessity criteria is applied for the remaining days.

c) During the course of review, the reviewer should determine if an inpatient stay was the result of a complication of an outpatient procedure; if uncertain due to inability to obtain necessary information, the request is referred to the Medical Director or appropriate practitioner.

d) The determination rationale and appropriate denial code ~~(as noted in the grid above)~~ are entered in the medical management system and the notice of proposed action is generated.

Not Liable Denial

1) **Ineligible on Date of Service:** The requesting provider is advised that the member is not eligible with Healthy Blue, continued action is taken when applicable.

2) There are instances when the Medical Director (or appropriate practitioner) must review and render a determination for not liable reasons:
   a) **Non-Covered Service/Benefit**;
      ~~a)~~ i) The designated health plan clinical reviewer notifies the requesting practitioner of the health plan Medical Director (or appropriate practitioner) decision to deny the non-covered service/benefit and generates the denial notification letter.
         ~~i)~~ **NOTE:** If the requested service is non-covered under any circumstance, NCQA does not require a Medical Director (or appropriate practitioner) review of requests for medical services specifically excluded from the health plan's benefit plan.
   b) **Benefit Exhausted**; and
      ~~b)~~ i) The designated health plan clinical reviewer notifies the requesting practitioner of the health plan Medical Director (or appropriate practitioner) decision to deny extension of treatment and generates the appropriate denial letter.
   c) **Other Health Insurance** (OHI).
      i) If a member has OHI, existing authorization rules remain applicable. If authorization is required when Healthy Blue is the member's primary insurance, an authorization is required when Healthy Blue is secondary.
      ii) Do not try to redirect non-participating requests to a participating provider.
      iii) If OHI is reported by a member or provider that is not listed under coordination of benefits (COB) in the medical management system, or there is a discrepancy in the information, the associate:
         (1) Obtains as much information as offered during request review;
         (2) Notifies the Cost Containment Unit via email at ccuohi@amerigroupcorp.com; and
         (3) Proceeds with processing the request regardless of the member's OHI as long as the member remains eligible; the request is not denied due to OHI in these instances.
   d) In these instances, the decision and rationale of the Medical Director (or appropriate practitioner) is documented in the medical management system, the appropriate denial code ~~(as noted in the grid above)~~ is entered, and the notice of proposed action is generated.

Health Care Acquired Condition (HCAC)/Provider Preventable Condition (PPC) Denial

1) All applicable information is documented, the appropriate denial is entered in the medical management system, and the notice of proposed action is generated. Denial reasons include:
   a) Inpatient admission resulting from a HCAC during an ER visit or Observation stay;
   b) HCAC denial that occurred during the admission and the member has discharged; and
   c) Partial hospital days during an inpatient stay are denied.

2) Healthy Blue shall deny payments to providers for PPC as defined by LDH in the *Medicaid Services Manual*. PCC are defined in two (2) separate categories:
   a) HCAC as defined by the Centers for Medicare and Medicaid Services (CMS); and
      i) Louisiana Medicaid considers HCACs as identified by Medicare, other than deep vein thrombosis (DVT)/pulmonary embolism (PE) following total knee replacement or hip replacement surgery in pediatric and obstetric patients.
   b) Other provider preventable conditions (OPPC), such as surgery on a wrong body part, wrong surgery on a patient, or surgery on a wrong patient.
3) Healthy Blue requires all providers to report PPCs associated with claims for payment or member treatment for which payment would otherwise be made. The health plan reports all identified PCC to LDH in the format specified by LDH.

Medical Director Medical Necessity Decisions

1) All Medical Director decisions are documented and appropriately reflected in the medical management system. Documentation must contain the following:
   a) Criterion or guideline utilized to render the decision;
   b) Reference of the clinical information submitted by the provider;
   c) Informal reconsideration or peer-to-peer review results, if applicable;
   d) Decision rationale; and
   e) The name of the Medical Director (or appropriate practitioner) who rendered the decision must be referenced in the notes; and their user identification number must be populated in the Secondary Reviewer field.
2) Although medical necessity criteria are reviewed with each level of care request, these items are only guidelines and just one factor that is considered in medical necessity reviews. Because each level of care review represents a unique clinical scenario that may not be fully described by the guidelines, other considerations, including but not limited to things such as practice patterns and professional experience and judgement, may also be factored into each final medical necessity determination.

Informal Reconsideration

The informal reconsideration or peer-to-peer process allows the member (or provider/agent on behalf of a member) a reasonable opportunity to address a medical necessity denial decision by presenting evidence, and allegations of fact or law, in person as well as in writing. This can occur anytime during the review process. Informal reconsiderations should occur within one (1) working day of the receipt of request and be conducted between the provider rendering the service and the Healthy Blue Medical Director who made the adverse determination (or designated clinical peer). The informal reconsideration will in no way extend the thirty (30) day required timeframe for a Notice of Appeal Resolution. Refer to *Informal Reconsideration – LA* for the detailed policy and procedures.

NOTE: The member is allowed sixty (60) calendar days from the date on Healthy Blue's notice of action or inaction to request a formal appeal. If a member or provider requests a procedure or service that was previously denied within the last sixty (60) calendar days, refer the member/provider to their appeals rights; do not enter a new request. If a member or provider requests a procedure or service that was previously denied greater than sixty (60) calendar days, enter a new request.

~~Decision Standard Timeframes~~ Determination Timing and Notices

Each type of review request has a specific timeframe for completion of the review process. All timeframes begin with the request for review, and end with the issuance of the notification of determination. Healthy Blue complies with NCQA, Accreditation Association of Ambulatory Health Care (AAAHC), state and federal standards.

State contractual timing of service authorization decisions and notice of action are as follows:

1) Concurrent review determinations shall be made within one (1) calendar day of obtaining the appropriate medical information that may be required.
2) Eighty percent (80%) of standard service authorization determinations shall be made within two (2) business days of obtaining appropriate medical information that may be required regarding a proposed procedure or service requiring a review determination, with the following exceptions:
   a) All inpatient hospital service authorizations shall be made within two (2) calendar days of obtaining appropriate medical information.
   b) All Community Psychiatric Support and Treatment (CPST) and Psychosocial Rehabilitation (PSR) service authorizations shall be made within five (5) calendar days of obtaining appropriate medical information.
   ~~b)~~c) All determinations for behavioral health crisis response services that require Prior Authorization as expeditiously as the enrollee's condition requires, but no later than one (1) Calendar Day after obtaining appropriate clinical documentation.
3) All standard service authorization determinations shall be made no later than fourteen (14) calendar days following receipt of the request for service.
   a) The service authorization decision may be extended up to fourteen (14) additional calendar days if:
      i) The member, or the provider, requests the extension; or
      ii) Healthy Blue justifies (to LDH upon request) a need for additional information and how the extension is in the member's interest.
4) In the event a provider indicates, or Healthy Blue determines, that following the standard service authorization timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function, Healthy Blue shall make an expedited authorization decision and provide notice as expeditiously as the member's

health condition requires, but no later than seventy-two (72) hours after receipt of the request for service.

a) Healthy Blue may extend the seventy-two (72) hour time period by up to fourteen (14) calendar days if the member or if Healthy Blue justifies to LDH a need for additional information and how the extension is in the member's best interest.

5) Retrospective review determinations shall be made within thirty (30) calendar days of obtaining the results of any appropriate medical information that may be required, but in no instance later than one hundred eighty (180) days from the date of ~~service.~~ receipt of request for Service Authorization.

6) Healthy Blue shall not subsequently retract its authorization after services have been provided or reduce payment for an item or service furnished in reliance upon previous service authorization approval, unless the approval was based upon a material omission or misrepresentation about the member's health condition made by the provider.

~~6)~~7) Healthy Blue shall not use a policy with an effective date subsequent to the original Service Authorization request date to rescind its Prior Authorization.

~~7)~~8) For service authorization approval for a non-emergency admission, procedure or service, the provider shall be notified verbally or as expeditiously as the member's health condition requires but not more than one (1) business day of making the initial determination and ~~provided documented confirmation of such notification~~ provide written notification to the provider within two (2) business days of making the ~~initial certification~~ determination.

~~8)~~9) For service authorization approval for extended stay or additional services, the provider rendering the service, whether a health care professional or facility or both, and the member receiving the service, shall be notified verbally or as expeditiously as the member's health condition requires but not more than one (1) business day of making the initial determination and ~~provided documented confirmation of such notification~~ provide written notification to the provider within two (2) business days of making the ~~initial certification.~~ determination.

~~9)~~10) The member shall be notified, in writing using language that is easily understood by the member, of decisions to deny a service authorization request, to authorize a service in an amount, duration, or scope that is less than requested, and/or any other action as contractually defined. The notice of action to members shall be consistent with requirements in 42 CFR §438.404, 42 CFR §438.10 and 42 CFR §438.210, contractual requirements for member written materials, and any agreements that LDH may have entered into relative to the contents of member notices of denial or partial denial of services, regardless of whether such agreements are related to legal proceedings or out-of-court settlements.

~~10)~~11) The requesting provider shall be notified of a decision to deny an authorization or reauthorization request or to authorize or reauthorize a service in an amount, duration, or scope that is less than requested. The provider rendering the service, whether a health care professional or facility or both, is notified verbally or as expeditiously as the

member's health condition requires but not more than one (1) business day of making the initial determination and shall provide documented confirmation of such written notification to the provider within two (2) business days of making the ~~initial certification.~~ determination.

~~11)~~ 12) Failure to complete a request in a timely manner constitutes a denial and is considered an adverse action by Healthy Blue.

The following are NCQA decision and notification timeframe standards:

1) For urgent (expedited) preservice review, a decision and notification are required within seventy-two (72) hours (or three (3) calendar days) of receipt of the request.
2) For urgent concurrent review for pharmacy requests, a decision and notification are required within twenty-four (24) hours (or one (1) calendar day) of receipt of the request.
3) For behavioral health and non-behavioral health (physical health) urgent concurrent reviews, a decision and notification are required as expeditiously as the member's health condition requires, but no later than within seventy-two (72) hours (or three (3) calendar days) of receipt of the request.
4) For non-urgent preservice review, a decision and notification is required within fourteen (14) calendar days from the receipt of the request.
5) For post-service review, a decision and notification is required within thirty (30) calendar days of receipt of the request.
6) For a reconsideration Review, a decision and notification is required within twenty-four (24) hours (or one (1) business day) of receipt of the urgent preservice or urgent concurrent request. A decision and notification is required within seven (7) business days of receipt of the non-urgent preservice or post-service request.
7) A possible extension of the above timeframes may occur if:
   a) The member or practitioner, acting as the member's authorized representative, voluntarily agrees to extend the decision-making timeframe; or
   b) The health plan justifies the need for additional information and how the extension is in the member's best interest to the appropriate state agency if required.
8) The initial oral or fax notification must reflect the time and date notification occurred, and who provided the notification.
9) The written notification must be issued no later than three (3) calendar days after the initial oral or fax notification, and reflect the date the notification was created.

NOTE: NCQA does not require an initial oral notification of a determination for urgent preservice and urgent concurrent reviews. Healthy Blue records the date, time, and associate who spoke with the provider and/or member for all notifications.

- A voicemail is not an acceptable form of oral notification.
- A fax may be sent as the initial notification. For urgent concurrent denials, the fax should include a statement asking the hospital Utilization Review (UR) department staff to notify the attending/treating practitioner of the decision.

- Electronic or written notification must be provided no later than three (3) calendar days after the initial notification.

Notice of Adverse Benefit Determination

1) The health plan provides written notification of adverse decisions to the member and requesting practitioner.
2) The written Notice of Action must explain and include the following:
   a) Statement of action Healthy Blue or its contractor has taken or intends to take;
   b) Explanation or reasons for the action or denial in easily understood language that is specific to the member and meets state-required reading levels;
   c) Availability of interpretation services for all languages, free of charge, and how to access them;
   d) Specific reference to utilization criteria guidelines, protocols or benefits provisions used in the determination;
      i) If the denial is due to lack of clinical information and there is insufficient clinical information to reference a specific guideline or criterion (for a given condition, service request), the notification must state the inability to reference the most appropriate criteria, and must describe the information needed to render a decision in a manner specific enough for the member or member's authorized representative to understand what is needed.
   e) The member's right to obtain, upon request and free of charge, copies of all documents, records, and other information relevant to the adverse benefit determination. Such information includes the actual benefit provision, medical necessity criteria, guidelines, protocol or other similar criterion on which the denial was based, and any processes, strategies, or evidentiary standards used in setting coverage limits;
      i) Medical management criteria and practice guidelines are posted to Healthy Blue's website. Practice guidelines are disseminated to all affected providers and, upon request, to members and potential members.
      ii) The criteria for medical necessity determinations for mental health and substance use disorder benefits are available online and, upon request, in hard copy at no cost to any enrollee, potential enrollee, or provider per 42 CFR 438.915 and 438.236.
   f) Notification to practitioners about the availability of and how to contact a health plan Medical Director (or appropriate practitioner) to discuss denial decisions and/or request criterion; and
   g) The member or practitioner's right to file an appeal and the accompanying procedures and timeframes to request a routine or expedited appeal, along with the timeframes for the health plan to decide on the appeal.

i) The member, member's representative or practitioner acting on the member's behalf, has up to sixty (60) calendar days to file an appeal upon issuance of the notice of action letter. Once the timeframe has expired, any requests for services related to the case previously denied are processed as a new precertification.
ii) The circumstances under which an expedited resolution is available (for urgent preservice or urgent concurrent denials), and how to request it;
iii) The member's right to submit written comments, documents, or other information relevant to the appeal;
iv) The member's right to the appointment of a new, nonsubordinate person to review the appeal;
v) The member's rights to have benefits continue pending the resolution of the appeal, how to request that benefits be continued, and the circumstances under which the member may be required to pay the costs of these services;
vi) The member's right to represent himself/herself or designate legal counsel, a relative, a friend, or other spokesperson;
vii) The member's right to request an evidentiary hearing if one is available or a State agency hearing as applicable; or in cases of action based on change in law, the circumstances under which a hearing will be granted; and
viii) The member's right to request a state fair hearing or external organization review after health plan appeal procedures have been exhausted.

3) All written materials are available in alternative formats and in a manner that takes into consideration member's special needs, including those who are visually impaired or have limited reading proficiency. The health plan notifies all members, via the member handbook, that information is available in alternative formats and how to access those formats.
4) All written materials, regardless of the means of distribution, must comply with guidance outlined in 42 CFR §438.10, ~~and~~ 42 USC §1396u-(2)(d)(2)(A)(i), and 42 U.S.C. §1396u-2(a)(5), including:
   a) All member materials must be in a style and reading level that will accommodate the reading skills of MCO Enrollees. In general, the writing should be at no higher than a 6.9 grade level, as determined by any one of the indices below, taking into consideration the need to incorporate and explain certain technical or unfamiliar terms to assure accuracy:
      i) Flesch – Kincaid;
      ii) Fry Readability Index;
      iii) PROSE The Readability Analyst (software developed by Educational Activities, Inc.);
      iv) Gunning FOG Index;
      v) McLaughlin SMOG Index; or
      vi) Other computer-generated readability indices accepted by LDH.
   b) All written materials must be clearly legible with a minimum font size of ~~ten-point, preferably~~ twelve (12)-point, with exceptions otherwise approved by LDH.

~~c) All written materials must be in accordance with the *LDH "Person First" Policy, Appendix NNC.*~~

~~d)~~c) All multi-page written member materials must notify the member that real-time oral and American Sign language interpretation is available for any language at no expense to them, and how to access those services.

~~e)~~d) Alternative forms of communication must be provided upon request for persons with visual, hearing, speech, physical or developmental disabilities. These alternatives must be provided at no expense to the member.

~~f)~~e) The date of issue, the date or revision, and/or if the prior versions are obsolete shall be included in all member materials.

g) Except as otherwise indicated, Healthy Blue may develop their own materials that adhere to requirements or use State-developed model member notices. State-developed model notices must be used for denial notices and pharmacy lock-in notices.

5) Letters are sent out daily (with the exception of Sundays and federal holidays) by the Document Control Center (DCC). Notices of Action are mailed within the following timeframes:
   a) For termination, suspension, or reduction of previously authorized covered services, at least ten (10) days before the date of action. In cases of verified member fraud, or when LDH has facts indicating that action should be taken because of probable member fraud, this timeframe is shortened to at least five (5) days before the date of action (CFR § 431.214);
   b) By the date of action for the following:
      i) In the death of a recipient;
      ii) In receipt of a signed written member statement requesting service termination or giving information requiring termination or reduction of services (where he/she understands that this must be the result of supplying that information);
      iii) The recipient's admission to an institution where he/she is ineligible under the plan for further services;
      iv) The recipient's address is unknown and mail directed to him/her has no forwarding address;
      v) The recipient has been accepted for Medicaid services by another local jurisdiction;
      vi) The recipient's physician prescribes the change in level of medical care; or
      vii) As otherwise permitted under 42 CFR §431.213.
   c) For denial of payment, at the time of any action affecting the claim according to the terms and conditions outlined in the contract between the provider and Healthy Blue.
   d) For standard service authorization decisions that deny or limit services, as expeditiously as the member's health condition requires and within fourteen (14) calendar days following receipt of the request for service, with a possible extension of up to fourteen (14) additional calendar days, if:

i) The member, or the provider, acting on behalf of the member and with the member's written consent, requests extension; or
ii) Healthy Blue justifies (to LDH upon request) a need for additional information and how the extension is in the member's interest.

e) If Healthy Blue extends the timeframe in accordance with the specifications above, it must:
i) Make reasonable efforts to give the member prompt oral notice of the delay;
ii) Within two (2) days, give the member written notice of the reason for the decision to extend the timeframe and inform the member of the right to file a grievance if he or she disagrees with that decision; and
iii) Issue and carry out its determination as expeditiously as the member's health condition requires and no later than the date the extension expires.

f) On the date the timeframe for service authorization expires. Untimely service authorizations constitute a denial and are thus adverse actions.

g) For expedited service authorization decisions where a provider indicates, or Healthy Blue determines, that following the standard timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function, Healthy Blue must make an expedited authorization decision and provide notice as expeditiously as the member's health condition requires and no later than seventy-two (72) hours after receipt of the request for service.
i) Healthy Blue may extend the seventy-two (72) hours' time period by up to fourteen (14) calendar days if the member requests an extension, or Healthy Blue justifies (to LDH upon request) a need for additional information and how the extension is in the member's interest.

6) Healthy Blue shall not create barriers to timely due process. LDH conducts random reviews to ensure that members receive notices in a timely manner.

Act 330 (House Bill 424)

House Bill 424, relative to claim and PA denials, requires Louisiana Medicaid Managed Care Organizations (MCOs) to furnish PA requirements to providers within twenty-four (24) hours of a request, or make requirements available online through the insurer's website. MCOs are required to give written notice of PA denials within three (3) days of a denial determination. If a PA or claim denial is based upon an opinion or interpretation of law, regulation, policy, procedure, or medical criteria or guideline, MCOs must provide in the written notice either instructions to access the source in the public domain or provide a copy of the source. Act 330 went into effect August 1, 2019.

REFERENCES:

- Administrative Denial Appeal Process – LA

- Annual Audit of Health Plan Utilization Management Denial Files
- Associates Performing Utilization Review – LA
- Behavioral Health Member Appeals – Core Process
- CFR Title 42
- Clinical Criteria for Utilization Management Decisions – Core Process
- Clinical Information for Utilization Review – LA
- Concurrent Review (Telephonic and On-Site) – LA
- Emergency and Post-Stabilization Services – LA
- Governance of Utilization Management Practice
- Health Care Management Audit Policy – LA
- Health Care Management Denial – Core Process
- Informal Reconsideration – LA
- Louisiana State Contract
- Member Appeals – Core Process – LA
- NCQA Accreditation Standards and Guidelines
- Non-Covered and Cost-Effective Alternative Services – LA
- Observation – LA
- Out-of-Area, Out-of-Network Care – LA
- Precertification of Requested Services – LA
- Prior Authorization Liaison (PAL) Policy – LA
- Prohibiting the Use of Financial Incentives When Making Medical Necessity Determination
- Resolving Pended Claims and ActionGrams
- Retrospective Review – LA
- Updating and Auditing Notice of Proposed Action Letters and Appeals review Forms
- Use of Board-Certified Consultants (Medical/Behavioral Health) – Core Process
- Utilization Management Clinicians Responsibilities (Health Plan/Region)
- Utilization Management Medicaid Delegation and Oversight

RESPONSIBLE DEPARTMENTS:

Primary Department:
Health Care Management – Utilization Management

Secondary Department(s):
Behavioral Health
National Customer Care Organization
Provider Services
Quality Management

EXCEPTIONS:

Healthy Blue shall provide a mechanism to reduce inappropriate and duplicative use of health care services. Services shall be sufficient in amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to ~~eligibles~~ beneficiaries under fee-for-service Medicaid, as specified in 42 CFR §~~438.210(a).~~440.230 and for Enrollees under the age of twenty-one (21), as set forth in 42 CFR Part 441, Subpart B. [42 CFR §438.210(a)(2)]. Upward variances of amount, duration and scope of these services are allowed.

Healthy Blue shall ~~provide core benefits and services, and~~ cover medically necessary services that address:

- The prevention, diagnosis and treatment of a member's disease, condition, and/or disorder that results in health impairments and/or disability;
- The ability for a member to achieve age-appropriate growth and development; and
- The ability for member to attain, maintain, or regain functional capacity.

Healthy Blue shall ensure that services are sufficient in amount, duration, and scope to reasonably be expected to achieve the purpose for which the services are furnished. Healthy Blue shall not arbitrarily deny or reduce the amount, duration, or scope of a required service because of diagnosis, type of illness, or condition of the member.

Healthy Blue may place appropriate limits on a service:

1) On the basis of certain criteria, such as medical necessity or best practices;
2) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose;
3) For the purpose of utilization control, provided the services support members with ongoing or chronic conditions in a manner that reflects the member's ongoing need for such services and supports; or
4) Provided family planning services are provided in a manner that protects and enables the member's freedom to choose the method of family planning to be used.

Healthy Blue may exceed the service limits as specified in the Louisiana Medicaid State Plan provided those service limits can be exceeded, with authorization, in fee-for-service.

Appropriate limits may be placed on a service on the basis of medical necessity or for the purposes of utilization control (with the exception of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services), provided the services furnished can reasonably be expected to achieve their purpose in accordance with 42 CFR §438.210. No medically necessary service limitation can be more restrictive than those that currently exist under the Louisiana Medicaid State Plan including quantitative and non-quantitative treatment limits. Healthy Blue may

limit services to those which are medically necessary and appropriate, and which conform to professionally accepted standards of care.

Healthy Blue shall use LDH's medical necessity definition as defined in LAC 50:I.1101 (Louisiana Register, Volume 37, Number 1) for medical necessity determinations, and make medical necessity determinations that are consistent with the State's definition. The Medicaid Executive Director in consultation with the Medicaid Medical Director ~~and Medicaid Behavioral Health Medical Director will make the final interpretation of any disputes about the medical necessity and continuation of core benefits and services based on whether or not the Medicaid fee-for-service program would have provided the service.~~ may require Healthy Blue to authorize services on a case-by-case basis.

In addition to services covered under the Louisiana Medicaid State Plan, Healthy Blue may cover any services necessary for compliance with the requirements for parity in mental health and substance use disorder benefits in 42 CFR Part 438, Subpart K.

Healthy Blue shall comply with all court-ordered requirements of Chisholm v. Gee (refer to *Prior Authorization Liaison (PAL) Policy – LA* for Chisholm requirements) and the terms of the Louisiana Department of Justice (DOJ) Agreement (Case 3:18-cv-00608, Middle District of Louisiana) in the manner directed by LDH.

Healthy Blue shall provide pregnancy-related services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of being pregnant and includes but is not limited to prenatal care, delivery, postpartum care, and family planning services for pregnant women in accordance with 42 CFR Part 440, Subpart B.

Healthy Blue shall not avoid costs for services covered in its Contract by referring enrollees to publicly supported health care resources.

~~Healthy Blue shall not portray core benefits or services as a value-added benefit or service.~~
Value-added benefits and services ~~are not Medicaid-funded and, as such,~~ are not subject to appeal and state fair hearing rights. A denial of these benefits will not be considered an adverse benefit determination for purposes of grievances and appeals. Healthy Blue shall send the member a notification letter if a value-added benefit or service is not approved.

Healthy Blue shall cover any item or service provided to an enrollee participating in a qualifying clinical trial to the extent that the item or service would otherwise be covered for the enrollee when not participating in the qualifying clinical trial. This includes any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation.

Exceptions to utilization management requirements:

1) Healthy Blue shall not require service authorization for emergency services or post-stabilization services as described in the Contract, whether provided by an in-network or out-of-network provider.
2) Healthy Blue shall not require service authorization or referral for EPSDT screening services.
3) Healthy Blue shall not require service authorization for the continuation of medically necessary covered services of a new member transitioning into the health plan, regardless of whether such services are provided by an in-network or out-of-network provider, however, prior authorization of services may be required beyond thirty (30) calendar days.
4) Healthy Blue is prohibited from denying prior authorization solely on the basis of the provider being an out-of-network provider for the first thirty (30) days of a newly enrolled member's linkage to the plan.
5) Healthy Blue shall not require a primary care physician (PCP) referral (if the PCP is not a women's health specialist) for access to a women's health specialist contracted with the plan for routine and preventive women's healthcare services and prenatal care.
6) Healthy Blue shall not require a PCP referral for in-network eye care and vision services.
7) Healthy Blue may require notification by the provider of obstetrical care at the time of the first visit of the pregnancy.
8) Healthy Blue shall not require hospital service authorization for non-emergency inpatient admissions for normal newborn deliveries.
9) Healthy Blue may require notification by the provider of obstetrical admissions exceeding forty-eight (48) hours after vaginal delivery. Healthy Blue is allowed to deny a portion of a claim for payment based solely on lack of notification by the provider of obstetrical admission exceeding forty-eight (48) hours after vaginal delivery. In this case, only the portion of the claim related to the inpatient stay beyond forty-eight (48) hours is denied.
10) Healthy Blue may require notification by the provider of obstetrical admissions exceeding ninety-six (96) hours after Caesarean section. Healthy Blue is allowed to deny a portion of a claim for payment based solely on lack of notification by the provider of obstetrical admission exceeding ninety-six (96) hours after Caesarean section. In this case, only the portion of the claim related to the inpatient stay beyond ninety-six (96) hours is denied.
11) Healthy Blue shall not deny continuation of higher level services (e.g., inpatient hospital) or residential treatment (e.g., therapeutic group home or psychiatric residential treatment facility) for failure to meet medical necessity unless it can provide the service through an in-network or out-of-network provider for a lower level of care.

Refer to *Non-Covered and Cost-Effective Alternative Services – LA* for information regarding excluded, non-covered, and in lieu of services.

REVISION HISTORY:

Section (Primary Department)	**SUBJECT (Document Title)**
Health Care Management - Utilization Management	**Health Care Management Denial - LA**

Review Date	Changes
04/23/2015	• Create Louisiana-specific version
05/02/2016	• For annual review • Updated language under policy to read if "The LA HP" verses "If a plan" • Definitions placed in alphabetical order
08/03/2017	• For annual review • Updated language to reflect Contract with Amendment 8 • DHH references changed to LDH • References placed in alphabetical order • Claims removed as secondary department • Departments placed in alphabetical order
07/26/2018	• For annual review • Primary Department updated • Minor updates to procedure section with current contract language
08/01/2019	• Annual Review • Placed on updated template • Updated Policy Section • Updated Definitions • Updated References
12/26/2019	• Off cycle review • Revised for new LA Emergency Contract • Wells v. Gee Class Settlement terminated 10/24/2019 • Policy title change from "Health Care Management Denial - Core Process – LA" to "Health Care Management Denial – LA" • Edits within policy, definition, procedure, exception, reference, and secondary department sections
09/10/2020	• Annual Review • Updated procedure
01/04/2021	• Off-Cycle Review • Contract Amendment 3 revisions made to the definitions and procedure
06/11/2021	• Off cycle review • Formatting updates • Contract Amendment 6 revision to Adverse Benefit Determination definition • Updated the "Effective Date" from 12/16/2009 to 04/23/2015 as the LA plan went live in 2012 & this also reflects the original policy creation date noted in the Revision History (this is a LA-specific policy created from a corporate policy version)

Section (Primary Department)	**SUBJECT (Document Title)**
Health Care Management - Utilization Management	**Health Care Management Denial - LA**

Review Date	Changes
08/20/2021	• Annual Review • Updated procedure to reflect UM process of notification and clinical information for clinical is the UM Medicaid Prior Auth Team; that team no longer reports under the NCC
07/08/2022	• Annual Review • Removed references to Facets Denial Codes • Updated procedure • Moved exceptions to correct place on template
05/17/2023	• Off Cycle Review • Revised Policy, Definition, Procedure, and Exceptions section • Removed definition for Qualified Practitioner • Added contract sections 2.12.4 and 2.12.5 • Added clinical trial requirements from MCO manual • Updated policy to align with current contract language and CFR Title 42