Coverage Criteria for Medical Services, Items and Medicare Part B Drugs

When Leon Health reviews a prior authorization request, they evaluate the medical necessity of the requested services or procedures, items or part B drugs using the InterQual™ criteria, the Medicare Coverage Database (MCD) or the CMS internet-only manuals. This typically involves comparing the details of the member's condition, medical history, and proposed treatment plan against the specific criteria outlined in the InterQual™ guidelines or in the Medicare Coverage Database (MCD) for that service or procedure, item or part B drug.

InterQual™ clinical criteria are evidence-based guidelines used by many health plans, including Leon Health, to assess the medical necessity of services or procedures, items, and part B drugs during the prior authorization process.

The Medicare Coverage Database (MCD) is a searchable database that contains comprehensive information about the coverage policies and guidelines for services and procedures, items and select part B drugs under Original Medicare.

The CMS internet-only manuals offer day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. These criteria help ensure that members receive appropriate, high-quality care based on the latest clinical evidence and best practices.

When coverage criteria are not fully detailed in InterQual™ the Medicare Coverage Database (MCD) or within the CMS internet-only manuals, Leon Health will create and publish internal coverage criteria. These criteria are developed based on current evidence from widely used treatment guidelines and publicly available clinical literature.

This approach ensures that Leon Health’s internal coverage criteria are comprehensive, scientifically valid, and aligned with the latest advancements in medical care. It also helps fill the gaps where InterQual™, the Medicare Coverage Database (MCD) or the CMS internet-only manuals might be lacking, ensuring members receive appropriate and necessary care.

You can access InterQual™ clinical criteria here: (you will need to create an Optum One Healthcare ID account to access the criteria)
https://prod.ds.interqual.com/service/connect/transparency?tid=b90a3bab-18bb-44f8-b73c-e4f069561148

Learn about InterQual™ Clinical Development Process here:
https://prod.cue4.com/help/InterQualOnline/MobileHelp/content/pdf/interqual%20development%20process%202024.pdf

You can access the Medicare Coverage Database (MCD) here:
https://www.cms.gov/medicare-coverage-database/search.aspx

You can access the CMS Internet-Only Manuals here:
https://www.cms.gov/medicare/regulations-guidance/manuals/internet-only-manuals-ioms

Leon Health, Inc. is an HMO with a Medicare contract. Enrollment in Leon Health, Inc. depends on contract renewal. ATENCIÓN: Si usted habla español, los servicios gratuitos de asistencia lingüística están disponibles para usted. También están disponibles de forma gratuita ayudas y servicios auxiliares apropiados para proporcionar información en formatos accesibles. Llame al 1-844-969-5366 (TTY:711) o hable con su proveedor. H4286_CCMSMPBD_C

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Policy Name:	Two Midnight Rule Inpatient Admission Policy		
Regulatory Citation:	42 CFR §412.3: https://www.ecfr.gov/current/title-42/section-412.3 Section 1852(g)(1)(A) of the Act: Social Security Act §1852 (ssa.gov) 42 CFR § 422.101(c): https://www.ecfr.gov/current/title-42/section-422.101 Medicare Coverage Database: MCD Search (cms.gov)		

1.0 POLICY

The two-midnight benchmark is part of the inpatient admission criteria outlined in 42 CFR §412.3. CMS requires all Medicare Advantage (MA) plans to adhere to the two-midnight rule as described in 42 CFR §412.3 which can be found @ https://www.ecfr.gov/current/title-42/section-412.3.

Please Note: Traditional Medicare also uses the term "two midnight presumption" which applies to medical review instructions for contractors under the Traditional Medicare program, not to MA plans. The following policy is applicable ONLY to the "two midnight benchmark for inpatient admissions as defined and cited above. Please see further clarification within this policy under the definitions.

CMS also requires all Medicare Advantage plans to follow the general coverage and benefit conditions which are included in Traditional Medicare for coverage of an inpatient stay. Medicare Advantage plans must follow all National and Local coverage determinations for Leon's service areas and benefit coverage conditions included in Traditional Medicare laws. This policy meets the intent for adherence to the above cited regulations governing the Medicare Advantage and Traditional Medicare programs.

As per this CMS issuance, Leon HP may use prior authorization or concurrent review of inpatient admissions for determination of the complex medical factors documented in the medical record do support the medical necessity of inpatient admission as cited by this policy.

The purpose of this policy is to define the process by which Leon shall conduct hospital admission review, both prospective and concurrent; for approval, modification, or denial of inpatient admissions.

2.0 SCOPE

The scope of the policy shall be applicable to all Leon staff, its FDRs (first tier/downstream entities), delegates or contracted vendor entities who conduct prior authorization, concurrent review, or retrospective review activities on behalf of Leon.

This policy shall outline the review process for the determination of the admission status of Leon's members based upon medical necessity according to the documentation of clinical record by the responsible admitting physician/provider using evidence-based criteria or guidelines for services while the member is currently in an emergency department, acute or post-acute setting awaiting admission status.

3.0 DEFINITIONS

Acute: Means sudden onset of illness or symptoms that develop quickly and in general, are expected to resolve in less than six months. Hemodynamically stable members who require treatment, assessment, or intervention every 4-8 hours.

Benefits: Health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

Critical Level of Care: Hemodynamically unstable members or those with the potential to become unstable, who require assessments or interventions every 1-2 hours as defined by InterQual® criteria.

Intermediate Level of Care: Hemodynamically stable members who require treatment, assessments, or interventions every 2-4 hours, as defined by InterQual® criteria.

Local Coverage Determination: The term local coverage determination means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).

MA plan: As defined by CMS means health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan (or in individual segments of a service area, under § 422.304(b)(2)).

Observation: Hemodynamically stable members who require at least 6 hours, and for certain conditions, up to 48 hours of treatment or assessments pending a decision regarding the need for additional care. Observation levels of care may be provided in designated locations such as an observation unit, hospital floor or a step-down unit. Observation services are defined as the use of a bed and periodic monitoring by a hospital's nursing or other ancillary staff, which are reasonable and necessary to evaluate an outpatient's condition to determine the need for possible inpatient admission.

Two-midnight presumptions: is a term used in the Traditional or Original Medicare program and is a medical review instruction given to Medicare post-payment audit and compliance contractors to help in the selection of claims for post-payment medical necessity reviews in Traditional Medicare. This term does not apply to MA plans decisions about how/when to engage in review of a particular inpatient stay.

4.0 PROCEDURE

Policy Name:	Two Midnight Rule Inpatient Admission Policy
Regulatory Citation:	42 CFR §412.3: https://www.ecfr.gov/current/title-42/section-412.3 Section 1852(g)(1)(A) of the Act: Social Security Act §1852 (ssa.gov) 42 CFR § 422.101(c): https://www.ecfr.gov/current/title-42/section-422.101 Medicare Coverage Database: MCD Search (cms.gov)

The clinical documentation for determining if an inpatient admission is reasonable and necessary for approval/certification of an inpatient admission must be based upon the medical/clinical judgement of the physician/practitioner and include:

- Validation/authentication of the physician/practitioner order:
  - The order must be completed, signed, dated, and documented
  - Must be prior to discharge
- The physician completing the order must:
  - Be responsible for the member or have sufficient knowledge of the case and be able to certify admission is required: This includes the following:
    - Admitting physician of record
    - Physician on call
    - Primary or covering hospitalist
    - Primary Care Provider or the on-call provider
    - Surgeon responsible for the procedure
    - ER or clinic practitioners who are caring for the member at the time of admission
- The reason for the inpatient services
- The estimated or actual required hospital time:
  - The two-midnight benchmark does require the physician to account for the total contiguous time in the hospital when formulating the expected length of stay. All documentation must support this expectation.
  - The order for admission cannot be retrospective. The inpatient stay begins with the order.
- Order for inpatient admissions may NOT be a standing order
- Clinical review protocol may be used, see below within this document

A qualified physician/practitioner must complete the formal admission process.

Verbal Orders:

Practitioners who do not have admitting authority, such as nurses, may be permitted to accept and record verbal orders at the designated facility; however:

- The ordering physician/practitioner must directly communicate the order and must countersign the order as written to authenticate the order
- The inpatient stay clock begins with the verbal order, if authenticated

Medical necessity must be determined based upon:

- Coverage and benefit criteria

- Whether the items/services ae reasonable and necessary
- The member's medical history (e.g., diagnosis, conditions, and functional status)
- Physicians recommendations and;
- Clinical notes

Leon HP must provide coverage and arrange for services for an inpatient admission and consider complex medical factors, as documented in the medical record for admission criteria, under 42 CFR 412.3 (d)(1) and (3), as follows:

- The admitting physician expects the member to require hospital care that crosses two midnights
- The admitting physician does not expect the member to require care that crosses two midnights, however, determines based on complex medical factors that are documented in the medical record, that inpatient care is necessary
- The inpatient admission is for a surgical procedure as specified by the Medicare as inpatient only.

Consistent with the regulations, Leon HP should defer to the judgement of the physician as long as this judgement is reasonable based upon the complex medical factors as documented in the medical record.

The qualified Leon prior authorization or concurrent review nurse/physician review must determine the need for hospital-based services by applying criteria. If a patient meets criteria at any level of care, then they have met the medical necessity requirement of the rule.

The reviewer must determine whether the patient is appropriate for inpatient or observation status depending on which level of care is met and the expected length of stay. Based on the presentation of the patient, evidence-based criteria such as InterQual can support the provider's expectation for length of stay.

Follow the guide below to determine inpatient OR outpatient status:

If…..	**Then…..**
Care is **expected to span 2 midnights** and the patient has met criteria for acute, intermediate, or critical level of care	Inpatient status may be appropriate to approve as per the above. Please Note: CMS states that in the event of unforeseen circumstances which may result in a shorter stay, the status of inpatient admission may still be appropriate. Such instances are: • Leaving against medical advice or AMA • Unexpected death • Transfer of the member

	• Unexpected clinical/condition improvement • Member elects hospice
Care is expected to span **less** than 2 midnights **but** acute, intermediate, or critical care criteria **are met.** **Note:** Outpatient observation services are not to be used as a substitute for medically necessary inpatient admissions. Outpatient observation services are not to be used for the convenience of the hospital, its physicians, patients, or patient's families, or while awaiting placement to another health care facility. Outpatient observation services must be patient specific and not part of the facilities standard operating procedure or protocol for a given diagnosis or service.	Assigning Observation status may be appropriate. (See exceptions below) • For stays for which the physician expects the member to need less than two midnights of hospital care (and the procedure is not on the inpatient-only list or otherwise listed as a national exception), an inpatient admission may be approved and payable by Leon on a case-by-case basis based on the judgment of the admitting physician. • The documentation in the medical record **must** support that an inpatient admission is necessary and is subject to medical review. Exceptions: CMS defines the following exceptions as being appropriate for inpatient status regardless of length of stay: • Mechanical ventilation established during current hospitalization • Surgical procedure or intervention found on the Inpatient Only List.
Undecided or unsure if care will span 2 midnights	Use the level of care met as a guide. • A patient who meets criteria at the acute level of care can be expected to have a length of stay of greater than 2 midnights and may be assigned to inpatient status. • Patients who meet criteria at the Observation level of care are more appropriate for observation status.

Outpatient Observation Status	Outpatient observation status services may be considered covered only when provided under a physician's order. Outpatient observation services are not to be used as a substitute for medically necessary inpatient admissions. Outpatient observation services are not to be used for the convenience of the hospital, its physicians, the member, or the member's families, or while awaiting placement to another health care facility. Outpatient observation services must be member specific and not part of the facilities standard operating procedure or protocol for a given diagnosis or service.

Transfers:

The concurrent review staff shall manage transfers under this policy in accordance with the following:

- Pre-transfer time and care provided to the member at the initial or transferring facility may be taken into account when determining if the 2-midnight benchmark was met.
- The "start clock" for transfers begins with care at the initial or transferring facility
- Excess wait times or times spent in the facility for non-medically necessary services must be excluded.

Clinical records should be requested from the transferring facility to support the medical necessity of the services that were provided and to very when the care for the member began.

Clinical Documentation

The applicable Leon nurse/physician reviewer staff shall reference the current clinical hierarchy process adopted by Leon Health Plan when performing review.

For inpatient review, the reviewer shall:

- Validate the eligibility of the member

- Validate the status of the provider to be contracted or non-contracted
- Using InterQual, conduct a primary review for medical necessity:
    - Select the most appropriate general or subset based upon symptoms/findings for the need of hospital services
    - Select and apply the appropriate episode day
    - Select the level of care: observation, acute, intermediate, or critical
    - Select criteria that are applicable to the case being reviewed
    - Conduct a secondary review if needed
        - Include the appropriate Medicare Coverage Guideline, CFR or Statute within the communication to the secondary reviewer.

I. Inpatient Concurrent Review Cases

a. Upon notification of admission at the health plan, the member inpatient case is transferred to Concurrent UM nurse for initial and concurrent review.

b. The Concurrent UM nurse is responsible for the collection of patient specific clinical information from the physician and/or the facility providing the services to the member. The information may be sent fax, telephonically, electronically or obtained onsite at the facility when applicable.

c. The Concurrent UM nurse is responsible for performing concurrent inpatient review management and discharge planning, including referrals to Care Management (CM) when applicable.

d. An initial and concurrent review is performed using evidence-based clinical guidance. The clinical information received shall be reviewed against this policy for all hospital admissions. The Concurrent UM Review nurse will perform the following process to document within the care management system the outcome determination:

1. Clearly document the clinical information used to support the review
2. Clearly document the Medicare coverage guidelines, CFR, Statute, clinical practice guidelines as per the LHP policies and InterQual® supporting the outcome determination
3. Outcome determination (favorable or adverse)
4. Any cased not meeting the clinical guideline criteria will be referred to the Medical Director for final outcome determination following the Medical Director Referral Review policy

5. Final outcome determination if case referred to the Medical Director
6. Notification of outcome determination to the provider, which should include:
    a. Date/time of determination notification
    b. To whom the information was provided and the mode of notification- telephonically, fax and/or electronic
    c. Next review date, if applicable
    d. If the outcome determination was a denial, Peer-to-Peer opportunity should be relayed to the provider with instruction and phone number to call for request

e. It is the Concurrent UM nurse's responsibility to perform the following activities:

1. Identify for elective admissions if a prior authorization was required. If there is no authorization on file, the case should be referred to the Medical Director for review and outcome determination.
2. Check on the procedures and service codes requested by the provider, including revenue codes (bed type on admission) with the number of units (days) identified in the Member's medical record
3. Identify and enter any diagnosis codes missing, including updating the admission diagnosis to primary diagnosis and secondary diagnoses once confirmed
4. Monitor the member's enrollment and eligibility status throughout the member's inpatient stay to ensure appropriate application of benefits.
5. Document initial and continued length of stay (LOS) record reviews and member assessments, as dictated by the Inpatient Rounds, and any status changes that may include:
6. Obtaining specific clinical information that support the medical necessity of a continued stay as determined by the approved criteria guidelines
7. Assistance with disposition of discharge and/or transitions of care (TOC) of the member
8. Identification, documentation, and reporting of any Hospital-Acquired Conditions (HAC's), referring all applicable cases to Quality-of-Care Concerns
9. Identification and coordination of all discharge needs for the member for a seamless transition of care at the time of discharge

10. Making referrals to Care Management if it is determined that a member may require CM service engagement for discharge planning (e.g., member is already in the CM Program or member is identified as most vulnerable, complex care or high dollar in services rendered):
    i. If a member is identified as already in the CM Program, the assigned Care Manager is to be notified.

f. The Concurrent UM nurse will follow the below timeframes for emergency/urgent admissions case reviews and outcome determinations:

- Initial/Concurrent case reviews will be conducted within 24-48 hours of the notification by the provider.
    1. If there is sufficient clinical information to support a medical necessity review, the outcome determination will be communicated to the provider within the first 24 hours after review has been complete
    2. If there is insufficient information to complete an initial/concurrent review, the Concurrent UM nurse will follow the procedure following the Lack of Information policy and provide the outcome determination provided no later than 72 hours after notification of the admission.

g. Reviews for extension of authorized services are not routinely done on a daily basis, but frequency is based on case complexity and severity of the member's condition as well as contractual agreements. Physicians and providers are instructed to communicate clinical information necessitating the extension of services prior to the expiration of the previous authorization period.

h. Using the LHP applications, the concurrent reviewer documents:
    1. Appropriate clinical information
    2. Criteria used, including date/version
    3. Review outcome
    4. Peer-to-Peer offer, when applicable

i. The concurrent review determination is based on the medical information received from the provider at the time medical care is provided and on evidence-based clinical criteria to be followed.

j. The Concurrent UM nurse may need to request additional clinical information from the requesting provider in order to determine medical necessity and appropriateness of requested services according to the Lack of Information policy.

k. If after reviewing all the clinical information, the Concurrent UM nurse is unable to authorize the member's extended stay, the case and clinical information is referred for review by the LHP Medical Director per the Medical Director Review policy.

l. A decrease in level of care or termination of services to a member due to lack of clinical information to support the continued stay is issued in a timeframe to accommodate a member/provider request and receipt of a review (appeal) determination prior to any reduction or termination based on CMS regulatory guidelines, see the Medicare Notification of Outcome Determinations policy.

- Written notification of the decision must be provided to the member and the provider as the member's health condition requires, but no later than 72 hours after receiving a request for an extension
- If LHP provides verbal notification to the member and provider of its decision, it must deliver a written confirmation of its decision within 3 calendar days of the verbal notification
- The Concurrent UM nurse is responsible for initiating the generation and ensuring the issuance of the outcome determination notification letter when applicable.

m. All continued stay review outcomes are communicated to the requesting provider, facility or member through phone, fax, written or electronic interface as defined by the LHP contractual agreement and/or according to state law.

n. A decrease in level of care, Inpatient to Observation, is based on the medical information received from the provider at the time medical care is provided and on evidence-based clinical criteria.

- Using InterQual, the Concurrent UM nurse conducts a primary review for medical necessity:
  - Select the most appropriate general or subset based upon symptoms/findings for the need of hospital services
  - Select and apply the appropriate episode day
  - Select the level of care requested: acute, intermediate, or critical
  - Select criteria that are applicable to the case being reviewed
  - Conduct a secondary review (if needed)
    - Include the appropriate Medicare Coverage Guideline, CFR or Statute within the communication to the secondary reviewer.

o. If after conducting the primary review for medical necessity the Concurrent UM nurse is unable to authorize the member's initial as requested, the case, clinical information (including InterQual's supporting outcome determination), the applicable Medicare coverage guideline, CFR, Statute, or clinical practice guidelines is referred for review by the LHP Medical Director per the Medical Director Review policy.

4.0 REVISION HISTORY

Date	Revision #	Description of Change
11.07.24	0.0	Creation

5.0 INQUIRIES

Direct inquiries about this policy to:
Health Services