

## **Standardized Formatting of Internal Criteria Instructions for Compiling and Submitting Criteria**

### **Part 1: Coverage Criteria for Medicare Advantage**

Organizations must enter all information as requested in the following fields.

#### Service Name:

- Criteria should be clearly identified by the name of the Medicare service
- If an organization uses multiple criteria documents or tools for a specific service the organization may either:
  - Fill out a unique form for the specific service indications (e.g., CT scan of ankle), or
  - Fill out one form including all criteria for a specific service (e.g., CT scans)

#### Criteria Name or Identifier

- Organizations must enter the name and/ or identifier that they have assigned to the item or service coverage criteria.
- The criteria name or identifier submitted on the standardized form should match the name and/or identifier of its publicly accessible version, if applicable.

#### Date Coverage Criteria Last Updated

- Enter the MM/DD/YYYY that the coverage criteria were last revised for any reason.
- If the coverage criteria have never been revised since implementation, enter the date the coverage criteria were first implemented by your organization.

#### Coverage Criteria Unique Weblink

- Enter the active and publicly accessible weblink (Uniform Resource Locators, URL) that provides direct access to the specific coverage criteria.

#### Applicable Coverage Area:

- Organizations must enter what localities this criteria applies to within their service area.
- Enter localities by locality number.
- Organizations may enter “All” if the criteria is applicable in all localities.

#### Coverage Criteria Applicable to Medicare Members:

- Organizations must enter all coverage criteria utilized for **Medicare members** into this field.
- All coverage criteria from any internal criteria documents or tools should be entered in this field.

- Organizations must not enter criteria applicable to commercial members or other lines of business unless that criteria is utilized to render medical necessity decisions for Medicare members.

#### Applicable Medicare Rules:

- Enter Yes or No if there are applicable Medicare rules related to this service.
- Applicable Medicare rules may include statute, regulation, manual, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) or Local Coverage Articles (LCAs).

#### Medicare Coverage Included or Excluded:

- Organizations must identify whether the coverage criteria entered in the third row (Coverage Criteria) includes criteria directly taken from Medicare coverage rules (such as NCDs or LCDs) or excludes Medicare rules.
- Organizations should enter “includes” if any specific requirements directly correspond to a Medicare coverage requirement.
- Organizations should enter “exclude” if all coverage criteria is unique from Medicare rules and does not overlap any specific requirements.

#### Explicit Flexibility for Additional Coverage:

- If the organization determined that either an NCD or LCD related to this specific service explicitly allows for coverage beyond the indications in the NCD or LCD enter the following:
  - The source citation for the NCD or LCD that contains that language (e.g., NCD 220.1)
  - Enter the specific language from the source identified that explicitly allows for additional coverage.
- If the NCD or LCD does not explicitly allow for additional coverage, enter NA.

### **Part 2: Analysis for Internal Coverage Criteria**

This chart must be filled out for all services. This table is only for internal criteria that is separate and distinct from requirements in Medicare rules. All **internal criteria** entered into Part 1 must be identified as unique requirements for coverage and included as separate line items into Part 2.

Example: In order to be approved/covered for an intrathecal pain pump the organization has criteria that requires the member have:

- Severe chronic intractable pain as defined by greater than 6 on the NRS pain scale,
- A life expectancy of at least 3 months, and

- No known active infection.

Each of these is a unique requirement that must be met for coverage. Each unique requirement that includes **internal coverage criteria** must be entered into a **separate line** in the table in Part 2.

**Columns A and B** must be filled out for each unique internal coverage criteria requirement.

**Columns C, D and E** must only be filled out when the internal coverage criteria is interpreting or supplementing a Medicare requirement.

Column A:

- Organizations should enter numbers starting with 1 for each separate requirement (internal coverage criteria).
- Organizations may add as many rows as needed based on the internal criteria for the service.
- Each internal criteria requirement must have its own unique identifier.

Column B:

- All unique requirements that are internal coverage must be entered as a separate line item in this field.

Column C:

Organizations should only fill out Column C when internal coverage criteria is interpreting or supplementing Medicare coverage rules.

- For each unique internal requirement identified in Column B that is either interpreting or supplementing a Medicare rule, enter the specific Medicare language that the internal criteria is supplementing.
- Language in Column C must be directly stated from a Medicare source (statute, regulation, manual, NCD or LCD)
- Organizations should not enter all Medicare language related to the service, but only that language that is being interpreted.

**Example:**

- Medicare coverage rules in an NCD indicate coverage for those members experiencing severe pain.
- The organization defined (interpreted) severe pain as being greater than 6 on the NRS pain scale.
- Column B would include “Greater than 6 on the NRS pain scale”
- Column C would include “severe chronic pain”

#### Column D:

Organizations should only fill out Column D when internal coverage criteria is interpreting or supplementing Medicare coverage rules.

- Include the specific Medicare source citation associated with the language included in Column C.
- The source should be as specific as possible when appropriate. For example, a direct regulatory citation (412.3(d)) is preferable to a general citation.

#### Column E:

Organizations should only fill out Column E when internal coverage criteria is interpreting or supplementing Medicare coverage rules.

- Organizations should include a statement on how this specific internal coverage criteria provides a clinical benefit that is highly likely to outweigh clinical harms.

### **Part 3: Evidentiary Support for Internal Coverage Criteria**

This chart must be filled out for all services. For each unique internal coverage criteria statement included in Part 2, a specific source or sources must be identified in Part 3. The sources should be specific to the internal coverage criteria they support.

#### Column A:

- The organization should enter a row for each unique identifier from Part 2.
- Each unique identifier in Part 2 should also be identified in Part 3.

#### Column B:

- Enter all references that specifically support the internal criteria associated with that unique identifier.
- Only include sources that directly support the criteria, do not include sources that just generally support the service.
- Include applicable page numbers for where the specific support for the criteria is located within the source.
- Enter all sources in MLA citation format.
- Multiple sources may be entered into a single line if there are multiple sources that support a specific internal coverage criteria requirement.

### **Part 4: Summary of Evidence/Rationale for Criteria**

Organizations may enter their summary of evidence and rationale for criteria in this section of the form.