CLINICAL GUIDELINES

Guideline Definitions

Effective Date: June 6, 2024

Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the Cigna CPT code list for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

Cigna-EviCore Co-branded Guideline Definitions

Definitions.A
v1.0.2024

Experimental, Investigational, or Unproven

Certain studies, treatments, procedures, or devices may be considered experimental, investigational, or unproven for **any** condition, illness, disease, injury being treated if one of the following is present:

- if there is a paucity of supporting evidence;
- if the evidence has not matured to exhibit improved health parameters;
- if clinical utility has not been demonstrated in any condition; OR
- the study, treatment, procedure, or device lacks a collective opinion of support.

Supporting evidence includes standards that are based on credible scientific evidence published in peer-reviewed medical literature (such as well conducted randomized clinical trials or cohort studies with a sample size of sufficient statistical power) generally recognized by the relevant medical community. Collective opinion of support includes physician specialty society recommendations and the views of physicians practicing in relevant clinical areas when physician specialty society recommendations are not available.

Medically Necessary

Healthcare services or supplies needed to diagnose, treat, or evaluate a condition or prevent an injury, illness, condition or disease that meets accepted standards of medicine based on evidenced-based clinical standards of care based on supporting evidence and/or collective opinion of support that is:

- Clinically appropriate in terms of type, frequency, extent, site, and duration, and considered effective for the individual's illness, injury or disease;
- Clinical utility of the technology, drug, device, treatment or procedure has been demonstrated for a diagnosis, treatment, evaluation or prevention of an illness, condition or disease based on evidence-based clinical standards of care;
- Not more costly than an alternative service or sequence of services that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of a condition;
- Not primarily for the convenience of the individual seeking medical services, health care provider, or other physicians or healthcare providers;

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- Supporting evidence and/or collective opinion of support does not demonstrate that there is an alternative that is more appropriate/effective for diagnosis, treatment, or evaluation of a condition.

Supporting evidence includes standards that are based on credible scientific evidence published in peer-reviewed medical literature (such as well conducted randomized clinical trials or cohort studies with a sample size of sufficient statistical power) generally recognized by the relevant medical community. Collective opinion of support includes physician specialty society recommendations and the views of physicians practicing in relevant clinical areas when physician specialty society recommendations are not available. Determination of medical necessity is based on specific clinical guidelines.

Not Medically Necessary

Certain studies, treatments, procedures, or devices may be considered not medically necessary if there is supporting evidence but one of the following is present:

- Not clinically appropriate in terms of type, frequency, extent, site, and duration, and/or not considered effective for the individual's illness, injury or disease;
- Clinical utility of the technology, drug, device, treatment or procedure has not been demonstrated for a diagnosis, treatment, evaluation or prevention of the specific illness, condition or disease based on evidence-based clinical standards of care;
- More costly than an alternative service or sequence of services that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of a condition;
- Primarily for the convenience of the individual seeking medical services, health care provider, or other physicians or healthcare providers;
- Supporting evidence and/or collective opinion of support demonstrates that there is an alternative that is more appropriate/effective for diagnosis, treatment, or evaluation of a condition

Supporting evidence includes standards that are based on credible scientific evidence published in peer-reviewed medical literature (such as well conducted randomized clinical trials or cohort studies with a sample size of sufficient statistical power) generally recognized by the relevant medical community. Collective opinion of support includes physician specialty society recommendations and the views of physicians practicing in relevant clinical areas when physician specialty society recommendations are not available. Determination of not medically necessary is based on specific clinical guidelines.

Special Considerations for Laboratory Testing

Laboratory-based testing is defined in terms of both the underlying technology used and, the indication for testing (i.e.: syndrome, condition, etc.). This is due to the ubiquitous use of specific technologies in laboratory medicine.

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References

1. **https://www.cigna.com/health-care-providers/coverage-and-claims/policies/medical-necessity-definitions**. Accessed 2023.04.03
2. **https://www.medicare.gov/glossary/m**. Accessed 2023.04.03
3. Per Compliance Internal policy: Clinical Certification of Services – Initial UM 0045:
    a. Experimental/Investigational: The use of a technology, drug, device, treatment, or procedure that has not been proven or recognized as having proven benefit in clinical medicine for any condition, illness, disease, or injury being treated.
    b. Medical Necessity: Refers to services or supplies for diagnosing, evaluating, treating or preventing an injury, illness, condition or disease, based on evidence-based clinical standards of care. Medically necessary services are accepted health care services and supplies provided by health care entities, appropriate to evaluation and treatment of a disease, condition, illness or injury and consistent with the applicable standard of care. Determination of medical necessity is based on specific clinical guidelines. (NCQA 2022 Standards; CMS; American College of Medical Quality)

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