

10.01.20 Investigational and Not Medically Necessary Services

Original Effective Date: June 2026

Review Date: June 2026

Revised:

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

Not applicable.

Summary

This policy provides a Wellmark framework for use by Utilization Management when there is no existing applicable state or federal requirement, no governing definition in the member's benefit plan, and no existing Wellmark medical policy that addresses the requested service. It sets forth Wellmark's contract-based definitions and decision framework for determining whether a service should be considered investigational or not medically necessary.

Note: This Wellmark medical policy is not an evidence review, but rather a descriptive document of whether a proposed service would be medically necessary or investigational in the absence of controlling legal, benefit-plan, or medical-policy direction.

OBJECTIVE

The objective of this policy is to support the proper determination of when a requested healthcare service should be classified as investigational or not medically necessary when there is no existing applicable state or federal requirement, no controlling definition in the member's benefit plan, and no existing Wellmark medical policy that addresses the service.

PRIOR APPROVAL

Not applicable.

Services that are novel, emerging, high-cost, or demonstrate unusual utilization patterns, including repeat billing, may be subject to additional prepayment, pre-service, or post-service review at Wellmark's discretion.

POLICY

Not medically Necessary

A service is considered not medically necessary when it does not meet Wellmark's contract definition of medical necessity.

A medically necessary healthcare service is one that a provider, exercising prudent clinical judgment, provides to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and satisfies all of the following:

- It is provided in accordance with generally accepted standards of medical practice. Generally accepted standards of medical practice are based on nationally recognized utilization management standards as utilized by Wellmark; or Wellmark's published medical and drug policies; or credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or physician specialty society recommendations and the views of physicians practicing in the relevant clinical area.
- It is clinically appropriate in terms of type, frequency, extent, site, and duration, and considered effective for the patient's illness, injury, or disease.
- It is not provided primarily for the convenience of the patient, physician, or other health care provider.
- It is not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the illness, injury, or disease.

If a requested service fails to satisfy the contract definition of medical necessity, the service is considered **not medically necessary**.

Wellmark may classify a service as not medically necessary, rather than investigational, when evidence has been stably insufficient for a prolonged period and further meaningful evidence evolution is unlikely, and there is consistent lack of support for medical necessity across relevant benchmarks, specialty-society recommendations, local practice patterns, and subject-matter-expert resources.

Investigational

A service is considered investigational when it has progressed to limited human application but has not achieved recognition as being proven effective in clinical medicine.

To determine investigational status, Wellmark considers whether the service, supply, device, or drug meets all of the following criteria:

1. It has final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence permits conclusions concerning its effect on health outcomes.
3. It improves the net health outcome.
4. It is as beneficial as any established alternatives.
5. The health improvement is attainable outside the investigational setting.

If the above criteria are not satisfied, the service is considered **investigational**.

Standard investigational policy language may include that the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

POLICY GUIDELINES

Note: *This policy applies when:*

1. *There is no applicable federal or state laws or regulatory requirements;*
2. *There is no benefit as outlined in member's benefit plan or other governing contract language;*
3. *There is no applicable Wellmark medical policy, drug policy, or other clinical guideline*

This policy is an administrative framework and should be applied with clinical judgment. The presence of regulatory clearance or approval, a CPT or HCPCS code, or the fact that a service is performed by a licensed provider does not by itself establish medical necessity or remove investigational status.

If a service is a covered benefit and a reviewer must apply clinical judgment because no specific criteria or policy exists, this policy may be used to support classification as investigational or not medically necessary consistent with the member contract and generally accepted standards of medical practice.

Note: While Wellmark may rely on these criteria, the final decision remains at the discretion of our Medical Director, whose decision may include reference to, but is not controlled by or limited to, peer-reviewed medical literature, physician specialty society recommendations, and the views of physicians practicing in the relevant clinical area.

Coding

See the [Codes](#) table for details.

Background

Not applicable.

SUPPLEMENTAL INFORMATION

Not applicable.

REFERENCES

Not applicable.

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

- Coding is variable depending on the device being requested.

POLICY HISTORY

Date	Reason	Action
June 2026	New policy.	New Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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