

## Not Medically Necessary, Experimental, Investigational and Unproven Guidelines, Medical 348

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**Member-specific benefits take precedence over medical policy and benefits may vary across plans.  
Refer to the individual's benefit plan for details [\\*](#).**

### Description & Definitions:

Sentara Health Plans limits coverage to devices, treatments or procedures for which the safety and efficacy have been proven, and are either comparable or superior to conventional, recognized standards of care. Not Medically Necessary, Experimental, Investigational and Unproven are terms the Plan uses to define the use of services to include, but are not limited to, diagnostic services, procedures, test, treatments, facilities, equipment, drugs or devices that are not recognized as standard medical care for the condition, disease, illness or injury being treated.

### Criteria:

**None**

Sentara Health Plans makes medical necessity determinations upon review of available Medical and Scientific Evidence as defined below. Evidence-based assessments of nationally recognized review organizations, physician specialty societal guidelines, and opinions of experts in the field may be considered by the Plan but are not determinative or conclusive.

Sentara Health Plans obtains Medical and Scientific Evidence from the sources noted below, to include but not limited to:

- Peer-reviewed scientific studies that have been published or have been accepted for publication by medical journals that meet recognized requirements for scientific manuscripts, whose published articles have been reviewed by experts who are not part of the editorial or study staff.
- Peer-reviewed literature or compendia from sources such as the National Institute of Health or The Cochrane Library.
- An accepted treatment indication from one of the following standard reference compendia:
  - The American Dental Association Accepted Dental Therapeutics,
  - The American Hospital Formulary Service-Drug Information,

- The American Medical Association Evaluations, and
  - The United States Pharmacopeia Drug Information.
- An accepted cancer treatment from one of the following standard reference compendia, or from FDA approved drugs for the treatment of cancer:
  - The Elsevier Gold Standard's Clinical Pharmacology,
  - The National Comprehensive Cancer Network Drugs, Biologics, or other Compendium,
  - The Thomson Micromedex DRUGDEX, and
  - Any other authoritative compendia recognized by the United States Secretary of Health and Human Services.
- Studies, research or findings conducted by or under the auspices of a recognized federal research institute or other federal government agency including, but not limited to:
  - Center for Medicare and Medicaid Services,
  - Federal Agency for Healthcare Research and Quality,
  - National Academy of Sciences,
  - National Cancer Institute,
  - National Institute of Health,
  - U.S. Department of Health and Human Services, and
  - Any national board recognized by the National Institute of Health whose purpose is to evaluate the medical value of health services.

Therefore, Sentara Health Plans considers a service to be Not Medically Necessary, Experimental, Investigational and / or Unproven if any of the following criteria are met:

- The supplies, services, or procedures that require Federal or other Governmental body approval, such as drugs and devices, do not have final unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body specifically for use in treatment of a specified condition.
- There is insufficient or inconclusive medical and scientific evidence (defined as at least two documents) available to allow for a thorough evaluation of the therapeutic value of the service, procedure or supply, and how the proposed treatment is likely to benefit the member.
- There is inconclusive or insufficient medical and scientific evidence in peer-reviewed medical literature that the service, procedure or supply has a beneficial effect on health outcomes beyond those available from conventional, recognized standards of care.
- There is inconclusive or insufficient medical and scientific evidence that, when used in a non- investigational setting, the service, procedure or supply has a beneficial effect on health outcomes beyond those available from conventional, recognized standards of care.
- Any procedure, treatment, device, or supply for which safety and efficacy has not been established and proven is considered investigational (unproven) and is considered to be not medically necessary or appropriate.

## Document History:

Revised Dates:

Reviewed Dates:

- September 2025 – Implementation date of January 1, 2026. Annual review. No changes to criteria. Updated to new format only.

Origination Date: 3/1/2025

## Coding:

Medically necessary with criteria:

Coding	Description

	None
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Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement.

Special Notes: \*

- Coverage
  - See the appropriate benefit document for specific coverage determination. Individual specific benefits take precedence over medical policy.
- Application to products
  - Policy is applicable to Sentara Health Plan Commercial products
- Authorization requirements
  - Pre-certification by the Plan is required.
- Special Notes:
  - Commercial
    - Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

## References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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### **Keywords:**

Experimental, Investigational, Unproven, Not Medically Necessary