# MN. 016.A Injectable/Specialty Drugs Prior Authorization Requirements

**Original Implementation Date** : 12/01/2019
**Version [A] Date :** 12/01/2019
**PARP Approved Date:** 01/29/2026
**Last Reviewed Date:** 02/18/2026

## PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans/Health Partners Plans lines of business unless noted below.

## PRODUCT STATEMENT

**A. Drugs and biologicals covered under the medical benefit are considered medically necessary when all the following criteria are met:**

1. It is a medically accepted indication defined by the following resources:
    - The Food and Drug Administration (FDA) approved indications (Drug package insert).
    - Nationally recognized compendia, such as Micromedex/Drugdex.
2. The dose is consistent with FDA-approved package labeling or nationally recognized compendia.
3. The off-label indication is listed in nationally recognized compendia for the determination of medically accepted indications for off-label use.
    - Medical necessity determination will also require review of scientific literature, clinical practice guidelines and local practice patterns.
    - Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.
4. The Non-Formulary or Non-preferred drug or biologic requires documentation that the patient has tried and failed the Formulary/Preferred agents (FDA approved or medically accepted for the patient's indication) OR a medical reason has been provided as to why these agents are unable to be used to treat the patient's condition (e.g., intolerance, contraindication, etc.).

**B. We do not cover drugs or biologicals that:**

1. Are experimental and investigational, or drugs that have not been proven safe and effective for a specific disease or approved for a mode of treatment by the Food and Drug Administration (FDA) and/or the National Institutes of Health.

2. Are drugs related to the treatment of non-covered services (Infertility injectable medications - unless coverage required by regulation; Steroids for the enhancement of performance, as this is not considered treatment of disease).

**C. Medical Director/clinical reviewer may override criteria when, in his/her professional judgment, the requested item is medically necessary.**

## POLICY GUIDELINES

1. Prior Authorization (PA) requirements for certain specific drugs are available on the provider and member websites.

2. This policy only applies in absence of a specific drug policy.

3. This policy is used when we receive PA requests for:

   - Drugs to be infused at home.
   - Drugs not included on the preferred drug list.
   - New FDA approved drugs.
   - Drugs for non-covered indications.
   - Admissions for drug infusions.

**Coverage of drugs and biologicals under the medical benefit will only be considered when:**

1. The drug or biologic is prescribed by or in consultation with an appropriate specialist.
2. Patient's specific factors preclude other ways of medication's administration (such as oral, transdermal, rectal etc.)
3. The drug or biologic is available on the preferred drugs list and is medically acceptable.
4. The drug or biologic is not available our or DHS preferred drugs list (PDL), but similar drugs from the same therapeutic drug class are available on lists. Coverage requires documented history of trial and

failure, or intolerance/ contraindication to the preferred drugs (FDA approved or medically accepted for the patient's indication).

5. There is drug or biologic specific PA guideline (policy), and PA requirements are not met. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.
6. There is no drug or biologic specific PA guideline, but the requested indication is medically accepted according to FDA approved package labeling or the national drug compendia resources, such as Micromedex. Medical necessity determination by a Medical Director will require review of scientific literature, clinical practice guidelines and local practice patterns. Medical Director also will take into consideration the availability of preferred drugs from different therapeutic drug classes that are medically acceptable for the same indication.
7. It is for an off-label indication listed in nationally recognized compendia for the determination of medically accepted indications for off-label uses. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient. Medical necessity determination by a Medical Director will require review of scientific literature, clinical practice guidelines and local practice patterns.
8. Prior Authorization for off-labeled use of medication requires a review on an individual basis by the Medical Director. It will be predicated on the appropriateness of treatment and full consideration of medical necessity.

## CODING

*Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.*



| CPT Code | Description |
|---|---|
| N/A | |

| HCPCS Code | Description |
|---|---|
| N/A | |

| ICD-10 Codes | Description |
|---|---|
| N/A | |

## BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the Member's applicable benefit contract on the date the service was rendered. Services determined by the Plan to be investigational or experimental, cosmetic, or not medically necessary are excluded from coverage for all lines of business.

## DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

For Health Partners Plans Medicaid and Health Partners Plans Chip products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

## POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

| Summary | Version | Version Date |
|---|---|---|
| 2026. Annual Review. No changes to policy criteria. References updated. | A | 12/01/2019 |
| 2025 Annual Review. No changes to policy. | A | 12/01/2019 |
| 2024 Annual review. No changes to policy. | A | 12/01/2019 |
| 2023 Annual review. No changes to policy. | A | 12/01/2019 |

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|---|---|---|
| 2022 Annual review. No content changes. References updated. | A | 12/01/2019 |
| 2021 Annual review. No changes to policy. | A | 12/01/2019 |
| 2020 Annual review. No changes to policy. | A | 12/01/2019 |
| This is a new policy bulletin. | A | 12/01/2019 |

## REFERENCES

1. IBM Micromedex - http://www.micromedexsolutions.com/micromedex2/librarian

2. Novitas Solutions, Local Coverage Article. Approved Drugs and Biologicals (A53049) https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53049

3. Our Medical Drugs that Require Prior Authorization (Medicaid) : Prior Authorization Drugs - Medicaid and CHIP

4. Our Medical Drugs that Require Prior Authorization (Medicare) : Prior Authorization Drugs - Medicare

5. Our Medical Drugs that Require Prior Authorization (Individual and Family Plans) : Prior Authorization Drugs - Individual and Family

6. Pennsylvania Preferred Drug List: Preferred Drug List