Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy

CENTENE® Corporation

Clinical Policy: Nanoencapsulated Sirolimus plus Pegadricase (NASP)

Reference Number: CP.PHAR.760
Effective Date: FDA Approval Date
Last Review Date: 12.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Nanoencapsulated sirolimus plus pegadricase (NASP®/™) consists of sirolimus, which is a targeted immunomodulator, and pegadricase, which is a PEGylated uricase enzyme.

FDA Approved Indication(s) [Pending]

NASP is indicated for the treatment of chronic gout in adult patients refractory to conventional oral therapies.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that NASP is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Chronic Gout (must meet all):

1. Diagnosis of chronic gout;*
2. Age ≥ 21 years;*
3. Positive for symptomatic gout with one or more of the following:
   a. At least 3 gout flares in the previous 18 months;
   b. At least 1 gout tophus;
   c. Chronic gouty arthritis;
4. Failure to normalize uric acid to < 6 mg/dL with allopurinol and febuxostat at maximally indicated doses, each used for at least 3 months unless clinically significant adverse effects are experienced or both are contraindicated;
5. Failure of probenecid, at maximally indicated doses, in combination with allopurinol or febuxostat unless clinically significant adverse effects are experienced or all are contraindicated;
6. NASP is not prescribed concurrently with oral urate-lowering agents (e.g., allopurinol, febuxostat, probenecid) or injectable urate-lowering agents (e.g., pegloticase);*
7. Dose does not exceed 0.2 mg/kg of pegadricase and 0.15 mg/kg of sirolimus every 28 days.*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*
**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Chronic Gout (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by a decrease in plasma uric acid levels;
3. NASP is not prescribed concurrently with oral urate-lowering agents (e.g., allopurinol, febuxostat, probenecid) or injectable urate lowering agents (e.g., pegloticase); *
4. If request is for a dose increase, new dose does not exceed 0.2 mg/kg of pegadricase and 0.15 mg/kg of sirolimus every 28 days.*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
allopurinol (Zyloprim®)	100 mg PO QD; may be increased by 100 mg every 2 to 4 weeks until serum urate concentration is ≤ 6 mg/dL or until maximum of 800 mg/day is reached	800 mg/day
febuxostat (Uloric®)	40 mg PO QD	80 mg/day
probenecid	250 mg PO BID for the first week, then 500 mg PO BID	2 gm/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): pending
- Boxed warning(s): pending

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
Chronic gout*	0.2 mg/kg of pegadricase and 0.15 mg/kg of sirolimus via intravenous infusion every 28 days *	See dosing regimen*

VI. Product Availability [Pending]

Pending

VII. References

1. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care & Research. June 2020; 0 (0): 1-17.
2. Swedish Orphan Biovitrum. A Study of SEL-212 in patients with gout refractory to conventional therapy I (DISSOLVE I). Clinicaltrials.gov. Last updated September 11, 2025. Available at: https://clinicaltrials.gov/study/NCT04513366. Accessed October 13, 2025.
3. Swedish Orphan Biovitrum. A Study of SEL-212 in patients with gout refractory to conventional therapy II (DISSOLVE II). Clinicaltrials.gov. Last updated February 20, 2024. Available at: https://clinicaltrials.gov/study/NCT04596540. Accessed October 13, 2025.
4. A. Kivitz, Singhal A, Patel A, et al. Pos0244 long-term improvements in serum uric acid levels, gout symptoms, and safety up to 12-months with sel-212 in gout refractory to conventional therapy: Results from the dissolve I phase 3, double-blind, placebo-controlled clinical trial. Annals of the Rheumatic Diseases. 2024;83. doi:https://doi.org/10.1136/annrheumdis-2024-eular.2875
5. Baraf HSB, Kivitz A, Rhodes S, et al. Lb0002 safety & efficacy of sel-212 in patients with gout refractory to conventional treatment: Outcomes from two randomized, double blind, placebo-controlled, multicenter phase III studies. Annals of the Rheumatic Diseases. 2023;82:200-201. doi:https://doi.org/10.1136/annrheumdis-2023-eular.7084

Coding Implications [Pending]

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Pending	Pending

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	11.04.25	12.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.