Louisiana Medicaid
Eflapegrastim-xnst (Rolvedon™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for eflapegrastim-xnst (Rolvedon™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning(s)** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- There is no preferred alternative that is:
  - The exact same chemical entity, formulation, strength, etc.; **OR**
  - FDA-approved biosimilar to the requested medication; **AND**
- If request is for a non-preferred agent - **ONE** of the following is required: (see Colony Stimulating Factors on the PDL/NPDL for list of preferred agents)
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
  - The prescriber states that the recipient is currently using the requested medication; **AND**
- **ONE** of the following is required:
  - The recipient has an approved diagnosis (or indication) for the agent requested (See Table 1);
    OR
  - For requests that do not include diagnoses/indications listed in the table below, support for use of the requested medication is noted on the request with references cited; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information, including absolute neutrophil count (ANC), have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Table 1. Diagnoses/Indications for Eflapegrastim-xnst (Rolvedon™)

Covered Diagnoses/Indications	Eflapegrastim-xnst (Rolvedon™)
Prophylaxis of febrile neutropenia in cancer patients receiving myelosuppressive chemotherapy for non-myeloid malignancies	X

Reference

Rolvedon (eflapegrastim-xnst) [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc; September 2022. https://www.rolvedon.com/pdf/rolvedon-prescribing-information.pdf

Revision / Date	Implementation Date
Policy Created / November 2022	April 2023