Reference number(s)
540-D

Initial Prior Authorization with Logic Uloric

Products Referenced by this Document

Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Uloric	febuxostat

Indications

FDA-approved Indications

Uloric is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.

For the safe and effective use of allopurinol, see allopurinol prescribing information.

Limitations of Use

Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

Screen out Code Logic

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30 day supply of allopurinol within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial screen out logic criteria, then the claim will

reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

Hyperuricemia

Authorization may be granted when the requested drug is being prescribed for the chronic management of hyperuricemia in an adult patient with gout when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response to a maximally titrated dose of allopurinol
- The patient has experienced an intolerance to allopurinol
- Treatment with allopurinol is contraindicated or inadvisable for the patient

Continuation of Therapy

Hyperuricemia

Authorization may be granted when the requested drug is being prescribed for the chronic management of hyperuricemia in an adult with gout when the following criteria is met:

- The patient has achieved or maintained a positive clinical response since beginning treatment with the requested drug

Duration of Approval (DOA)

- 540-D: DOA: 36 months

References

1. Uloric [package insert]. Lexington, Massachusetts: Takeda Pharmaceuticals America, Inc.; April 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 28, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/28/2024).

4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. Arthritis Rheumatol. 2020;72(6):879-895.

Document History

Written by: UM Development (SE) 11/2009

Revised: (CY) 09/2010 (made standard), 01/2011(added CI question); (CT) 04/2011 (no longer MDC-1/new MDC-2 was developed); (MS) 09/2011, 11/2011, 01/2012 (removed theophylline as contraindication to match current PI), 06/2012, 10/2012 (extended duration); (CT) 06/2013; (MS) 12/2013; (CF) 12/2014 (no grids needed), 12/2015, 06/2015 (no clinical changes); (MS) 12/2016 (removed contraindication question due to lack of denials), (SF) 12/2017; (RP) 11/2018 (no clinical changes); (KC) 11/2019; (CJM) 11/2020 (no clinical changes); (MRS) 11/2021 (updated document title); (CJH) 11/2022 (Added COT criteria, updated contraindication question wording to align with PI), (TM) 11/2023 (no clinical changes); ANB 11/2024 (no clinical changes)

Reviewed: Medical Affairs (WLF) 11/2009; (KP) 09/2010, 01/2011, 09/2011, 11/2011, 01/2012, 06/2012; (LCB) 06/2013, 12/2013; (DHR) 12/2014; (AN) 12/2016, (DC) 12/2017; (CHART) 11/27/2019, 12/3/2020, 12/2/2021, 12/1/2022, 11/30/2023, 11/21/2024

External Review: 12/2009, 12/2010, 02/2011, 03/2012, 10/2012, 08/2013, 04/2014, 04/2015, 02/2016, 02/2017, 02/2018, 02/2019, 02/2020, 02/2021, 02/2022, 02/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the chronic management of hyperuricemia in an adult patient with gout? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 4.]	Yes	No
3	Has the patient achieved or maintained a positive clinical response since beginning treatment with the requested drug? [No further questions]	Yes	No
4	Has the patient experienced an inadequate treatment response to a maximally titrated dose of allopurinol? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Has the patient experienced an intolerance to allopurinol? [If Yes, then no further questions. If No, then go to 6.]	Yes	No

6	Is treatment with allopurinol contraindicated or inadvisable for the patient? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for the chronic management of elevated uric acid levels in an adult patient with gout. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Go to 4	
3.	Approve, 36 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Efficacy]
4.	Approve, 36 Months	Go to 5	
5.	Approve, 36 Months	Go to 6	

6.	Approve, 36 Months	Deny	Your plan only covers this drug if you have tried allopurinol, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]