

Benzodiazepines and Antianxiety Agents
Byfavo (remimazolam)
Effective 06/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Byfavo is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization will be granted when all the following criteria has been met, and documentation has been submitted:

1. Agent will be used for induction and maintenance of procedural sedation
2. Physician attestation of inadequate response, adverse reaction, or contraindication to intravenous midazolam
3. Appropriate dosing

Continuation of Therapy

Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 1 month or until procedure date, if provided.
2. Reauthorizations will be treated as a new request and granted for 1 month or until procedure date.

References

1. Central Nervous System Agents 28:00, Anxiolytic, Sedatives 28:24, Benzodiazepines 28:24.08. In: McEvoy GK, editor; American Hospital Formulary Services. AHFS drug information 2012 [monograph on

the Internet]. Bethesda (MD): American Society of Health-System Pharmacists; 2012 [cited 2016 June 8]. Available from: <http://online.statref.com>.

2. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Truven Healthcare Analytics Inc.; Updated periodically [cited 2016 June 8]. Available from: <http://www.thomsonhc.com/>.
3. Thakeur RR, Kashi M. An unlimited scope for novel formulations as orally disintegrating systems: present and future prospects. *Journal of Applied Pharmaceutical Science* 2011; 1(01):13-19.
4. U.S. Food and Drug Administration. Regulatory Information: Food and Drug Administration Modernization Act of 1997 [webpage on the internet]. Rockville (MD): Food and Drug Administration (US); 2012 [cited 2016 June 8]. Available from: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDAMA/FullTextofFDAMALaw/default.htm#SEC.127>.
5. Byfavo [prescribing information]. Indianapolis (IN): Acacia Pharma, Inc.; 2025 Feb.

Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

04/12/23 – Reviewed and updated for Apr P&T. Clarified diagnoses throughout policy. Added QL criteria for triazolam 0.25 mg. Guideline update to reflect inclusion of hospice/palliative care in the COBI clinical criteria as rationales for using combination therapy. Benzodiazepine polypharmacy criteria was clarified to only apply to adult member reviews. Effective 6/5/23

05/10/23 – Reviewed and updated for P&T. Added provisional approvals for various circumstances. Updated polypharmacy criteria for seizure diagnosis to include taper therapy plan and one short acting and long acting benzodiazepine agent regimen. Effective 7/1/23.

07/12/23 – Reviewed and updated for P&T. Brand preferred and mandatory generic language was added under Limitations. Added diagnosis of seizure disorder as acceptable for approval of oxazepam and clorazepate. Updated approvable diagnoses for alprazolam ER. Moved Hypnotic benzodiazepine requests > 1 unit/day from Appendix. Formatting updates made to drug table. Effective 7/31/23.

09/13/23 – Reviewed and updated for P&T. Clarified Tranxene (clorazepate) criteria. Effective 10/2/23

05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. All agents except for Byfavo were pharmacy benefit only and thus have been removed. Updated formatting & references accordingly. Effective 6/1/25

