

Clinical Policy Title:	Off-Label Use
Policy Number:	RxA.601
Drug(s) Applied:	Off-Label Use
Original Policy Date:	03/06/2020
Last Review Date:	08/15/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. All Indications (must meet all):

1. Use is supported by one of the following (a or b):
 - a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;
 - b. Micromedex Drug Dex® with strength of recommendation Class I, IIa, or IIb;
2. Trial and failure of at least two formulary alternatives FDA-approved for the indication and/or drugs that are considered the standard of care, unless no such drugs exist, are contraindicated, or clinically significant adverse effect are experienced.

Approval Duration

All lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications:

1. One of the following (a or b):
 - a. Member is currently receiving medication that has been authorized by RxAdvance, excluding manufacturer samples.

Approval Duration

All lines of Business (except Medicare): 12 months

References

1. Food and Drug Administration. Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses - Recommended Practices. January 2009. Available at: <https://www.fda.gov/media/88031/download> . Accessed August 31, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title Table was updated 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving 	10/20/2020	12/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>medication that has been authorized by RxAdvance...".</p> <p>3. References was updated.</p>		
<p>Policy was reviewed:</p> <p>1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</p> <p>2. References were reviewed and updated.</p>	10/13/2021	12/07/2021
<p>Policy was reviewed:</p> <p>1. References were reviewed and updated.</p>	08/31/2022	10/19/2022
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed.</p> <p>1. Added Micromedex level of evidence 2B and NCCN level of evidence 2B.</p> <p>2. Removed dosing criteria.</p> <p>3. Removed contraindications and risk reduction criteria.</p> <p>4. Removed reauthorization requirement for positive response to therapy.</p> <p>5. Removed the ability to use clinical trials as evidence.</p>	8/14/2024	8/28/2024