

Initial Prior Authorization Select Medical Devices

Products Referenced by this Document

Ref # 2363-A: Select Medical Devices Rx Only

Brand Name
Use RxClaim List ID CMKJMED002 for target list

Ref # 2506-A: Select Artificial Saliva Medical Devices Rx Only

Brand Name
Use RxClaim List ID CMKJMED001 for target list

Coverage Criteria

Authorization may be granted when the requested drug is being used according to the manufacturer's indication when ALL of the following criteria are met:

- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ALL available FDA-approved drugs for their medical condition.
- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ALL available over-the-counter (OTC) products for their medical condition.

Duration of Approval (DOA)

- 2363-A: DOA: 3 months
- 2506-A: DOA: 12 months

References

1. Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed May 13, 2025.

Document History

Written by: UM Development (JK/TM/KC)

Date Written: 02/2018

Revised: (KC) 03/2019 (no clinical changes), 10/2020 (no clinical changes); (TM) 08/2021 (no clinical changes), 08/2022 (no clinical changes), 08/2023 (no clinical changes), 03/2024 (aligned qsets); VLS 08/2024 (no clinical changes), VLS 05/2025 (no clinical changes)

Reviewed: Medical Affairs (SD) 05/2018; (AN) 05/2019; (CHART) 10/29/20, 09/30/2021, 08/25/2022, 08/24/2023, 04/18/2024, 08/29/2024, 05/29/2025

MD Committee 05/2018, 05/2019, 12/2019, 10/2020, 11/2021, 08/2022, 08/2023, 04/2024, 10/2024

External Review: 11/2022 (MD Subcommittee), 12/2023, 10/2024, 11/2024, 06/2025

CRITERIA FOR APPROVAL

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|---|--|-----|----|
| 1 | Is the requested product being used according to the manufacturer's indication?
[If Yes, then go to 2. If No, then no further questions.] | Yes | No |
| 2 | Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to ALL available FDA-approved drugs for their medical condition?
[If Yes, then go to 3. If No, then no further questions.] | Yes | No |
| 3 | Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to ALL available over-the counter (OTC) products for their medical condition?
[No further questions] | Yes | No |

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	Your plan only covers this product when it is used for certain health conditions. Covered use is according to the manufacturer's

			<p>indication. Your plan does not cover this product 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 product, you may have to meet other criteria. You can request the product policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Go to 3	Deny	<p>Your plan only covers this product if you have tried other drugs and products and they did not work well for you. We have denied your request because: A) You have not tried all available FDA-approved drugs and over-the counter (OTC) products for your medical condition, and B) You do not have a medical reason not to take them. 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 product, you may have to meet other criteria. You can request the product policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step therapy]</p>
3.	Approve, 3 Months	Deny	<p>Your plan only covers this product if you have tried other drugs and products and they did not work well for you. We have denied your request because: A) You have not tried all available FDA-approved drugs and over-the counter (OTC) products for your medical condition, and B) You do not have a medical reason not to take them. 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 product, you may have to meet other criteria. You can request the product policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step therapy]</p>