Reference number(s)
478-D

Initial Step Therapy; Post Step Therapy Prior Authorization Antipsychotics

Generic Step Therapy Plans (GSTP)

Products Referenced by this Document

Brand Name
Caplyta
Fanapt
Lybalvi
Rexulti
Secuado
Versacloz
Vraylar

Initial Step Therapy

If the patient has filled a prescription for at least a 30 day supply of at least one generic atypical (second-generation) antipsychotic drug within the past 730 days OR has filled a prescription for Caplyta, Fanapt, Lybalvi, Rexulti, Secuado, Versacloz or Vraylar in the previous 730 days under a prescription benefit administered by CVS Caremark, then the requested branded drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy 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

Authorization may be granted for the requested drug when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response after at least a 30 day trial of at least ONE generic antipsychotic drug.
- The patient has a documented contraindication or a potential drug interaction that would prohibit a trial of at least ONE generic antipsychotic drug.
- The patient has experienced an intolerance to at least ONE generic antipsychotic drug.
- The requested drug is being prescribed for the treatment of agitation associated with dementia due to Alzheimer's disease and the following criteria is met:
    - The request is for Rexulti.

Continuation of Therapy

Authorization may be granted for the requested drug when the following criteria is met:

- The request is for continuation of therapy with the requested drug.

Duration of Approval (DOA)

- 478-D: DOA: 24 months

References

1. Rexulti [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; May 2024.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed September 9, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/09/2024).
4. U.S. Food and Drug Administration. FDA News Release: FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease. May 11, 2023. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease. Accessed September 9, 2024.

Document History

Written by: UM Development (NB)

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Revised: 06/2010 (added grandfathering), 01/2011, 05/2011, 10/2011, 09/2012, 10/2012 (removed documentation) , 09/2013 (re-worded question 2), 09/2014 (reordered questions), 07/2015 (removed Abilify), 07/2015 (added Adasuve & Rexulti), 09/2015 (added Vraylar), 09/2015, 10/2015 (removed

Invega), 11/2015 (added Invega Sustenna and Invega Trinza), 12/2015 (removed Invega Sustenna and Invega Trinza), 09/2106 (no changes), (SF) 09/2017 (no changes), 09/2018 (no changes), 01/2019 (removed Latuda), 07/2019 (added Latuda back, anticipated generic did not launch), 09/2019 (updated with template language), 09/2020 (no changes), (DFW) 04/2021 (removed Saphris), 09/2021 (no clinical changes); (CJH) 09/2022 (off-cycle - removed Adasuve from target drug list and initial ST pre-requisites; added continuation of therapy question), 09/2022 (annual review - no clinical changes), (DFW) 11/2022 (updated annual review to add Caplyta, Secaudo, Versacloz to target drugs and prereqs), (DFW) 04/2023 (removed Latuda from target drug list and initial ST), 05/2023 (added agitation indication for Rexulti), 06/2023 (added Lybalvi to target drug list and initial ST); (KEJ) 09/2023 (no clinical changes); (DFW) 09/2024 (no clinical changes); (KEJ) 11/2024 (updated look back to 730 days)

Reviewed: Medical Affairs, 02/2010, 01/2011, 10/2011; (DC) 09/2012, 09/2013, (SS) 09/2014, 07/2015, (LS) 09/2015, (MM) 09/2015, (EPA) 07/2019, (CHART) 09/26/2019, (CHART) 09/24/2020, (CHART) 04/08/2021, (CHART) 09/30/2021, (CHART) 09/22/2022, (CHART) 12/08/2022 (updated annual review), 04/20/2023, 05/18/2023, 06/15/2023, 09/28/2023, 09/26/2024, 12/05/2024

External Review: 03/2010, 12/2010, 12/2011, 02/2013, 12/2013, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 02/2019, 08/2019 (FYI), 12/2019, 12/2020, 06/2021 (FYI), 12/2021, 10/2022 (FYI), 12/2022, 06/2023 (FYI), 08/2023, 12/2023, 12/2024, 12/2024 (FYI)

CRITERIA FOR APPROVAL

1	Is this request for continuation of therapy with the requested drug? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Has the patient experienced an inadequate treatment response after at least a 30 day trial of at least one generic antipsychotic drug? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Does the patient have a documented contraindication or a potential drug interaction that would prohibit a trial of at least one generic antipsychotic drug? [If Yes, then no further questions. If No, then go to 4.]	Yes	No
4	Has the patient experienced an intolerance to at least one generic antipsychotic drug? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Is this request for Rexulti? [If Yes, then go to 6. If No, then no further questions.]	Yes	No

6	Is the requested drug being prescribed for the treatment of agitation associated with dementia due to Alzheimer's disease? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Approve, 24 Months	Go to 2	
2.	Approve, 24 Months	Go to 3	
3.	Approve, 24 Months	Go to 4	
4.	Approve, 24 Months	Go to 5	
5.	Go to 6	Deny	Your plan only covers this drug if you have tried at least one generic antipsychotic drug, 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]
6.	Approve, 24 Months	Deny	Your plan only covers this drug when: A) You have tried at least one generic antipsychotic drug, and it did not work well for you, B) You have a medical reason not to take a generic antipsychotic drug, or C) You are using it for agitation in dementia in someone with Alzheimer's disease. 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 - Rexulti]