UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2040-39
Program	Prior Authorization/Medical Necessity – Non-Solid Oral and Suppository Dosage Forms
Medication	Alkindi® Sprinkle (hydrocortisone)*, Arbli™ (losartan), Aspruzyo Sprinkle™ (ranolazine), Atmeksi® (methocarbamol), Atorvaliq® (atorvastatin), Brynovin™ (sitagliptin), Carospir® (spironolactone), chlorpromazine oral solution, Desmoda™ (desmopressin), Epaned® (enalapril), Eprontia® (topiramate)*, Ermeza™ (levothyroxine)*, Ezallor Sprinkle™ (rosuvastatin), Fleqsuvy® (baclofen), Flolipid (simvastatin), Imkeldi (imatinib), Indocin® (indomethacin) suspension, Indocin® (indomethacin) suppository, Inzirqo™ (hydrochlorothiazide), Javadin™ (clonidine), Jylamvo® (methotrexate), Katerzia® (amlodipine)*, Khindivi™ (hydrocortisone), Lopressor® (metoprolol) oral solution, Meloxicam (meloxicam) suspension, Naprosyn®* (naproxen) suspension, Nexium® for suspension (esomeprazole), Norliqva® (amlodipine), Ontralfy™ (tizanidine), Ozobax® DS (baclofen), Pradaxa® (dabigatran) oral pellets, Prevacid® SoluTab™ (lansoprazole), Prograf® Granules (tacrolimus), Qbrelis® (lisinopril), Raldesy™ (trazodone), Renvela® (sevelamer carbonate) powder for suspension, Sdamlo™ (amlodipine), Sotylize® (sotalol), Subvenite® (lamotrigine), Sympazan® (clobazam), Syndros® (dronabinol), Tezruly™ (terazosin), Tiglutik® (riluzole), Tirosint®-Sol (levothyroxine), Valsartan oral solution, Vyscoxa™ (celecoxib), Xatmep® (methotrexate), Xelstrym™ (dextroamphetamine), Xromi® (hydroxyurea), Zegerid® for suspension (omeprazole and sodium bicarbonate)*, Zonisade® (zonisamide)
P&T Approval Date	8/2014, 11/2014, 2/2015, 4/2015, 1/2016, 3/2016, 10/2016, 2/2017, 7/2017, 10/2017, 3/2018, 11/2018, 3/2019, 8/2019, 11/2019, 12/2019, 2/2020, 12/2020, 2/2021, 5/2021, 9/2021, 10/2021, 1/2022, 6/2022, 9/2022, 11/2022, 1/2023, 5/2023, 7/2023, 9/2023, 12/2023, 5/2024, 2/2025, 6/2025, 8/2025, 11/2025, 2/2026, 5/2026
Effective Date	8/1/2026

1. Background:

Coverage criteria outlined below are for patients unable to ingest a solid oral dosage forms. Claims for patients under the age of 6 will process automatically for Alkindi Sprinkle, Arbli, Brynovin, Carospir, chlorpromazine oral solution, Epaned, Fleqsuvy, Flolipid, Indocin, Inzirqo, Jylamvo, Khindivi, Lopressor oral solution, Meloxicam suspension, Naprosyn suspension, Nexium suspension, Norliqva, Ozobax DS, Prevacid SoluTab, Prograf Granules, Qbrelis, Raldesy TM, Simvastatin oral suspension (Flopid authorized generic), Sotylize, Subvenite, Tezruly, Tirosint-Sol, Vyscoxa, Xatmep and Xromi. Claims for patients under the age of 8 will process automatically for Pradaxa oral pellets. Claims for patients under the age of 19 will process automatically for Imkeldi.

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2. Coverage Criteria[a]:

A. **Alkindi Sprinkle, Arbli, Atmeksi, Atorvaliq, Brynovin, Carospir, chlorpromazine oral solution, Desmoda, Epaned^, Ermeza, Ezallor Sprinkle, Inzirqo, Fleqsuvy^, Flolipid, Indocin suspension^, Indocin suppository^, Jylamvo, Khindivi, Lopressor oral solution, Meloxicam suspension, Naprosyn suspension, Nexium suspension^, Norliqva, Ozobax DS, Pradaxa oral pellets, Prevacid SoluTabs, Prograf Granules, Qbrelis, Raldesy TM, Renvela powder for suspension, Simvastatin oral suspension (Flolipid authorized generic) Sotylize, Syndros, Tezruly, Tiglutik, Tirosint-Sol, Xatmep, Xromi and Zonisade** will be approved based on **ONE** of the following criteria:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia

-OR-

2. Patient utilizes a feeding tube for medication administration

Authorization will be issued for 12 months

B. **Zegerid suspension*** will be approved based on **BOTH** of the following criteria:

1. **ONE** of the following:

   a. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

      (1) age
      (2) oral/motor difficulties
      (3) dysphagia

-OR-

   b. Patient utilizes a feeding tube for medication administration

-AND-

2. Patient has a history of trial and failure, intolerance or contraindication to **BOTH** of the following:

   a. Nexium suspension (esomeprazole)
   b. lansoprazole orally disintegrating tablets (generic Prevacid SoluTabs)

Authorization will be issued for 12 months

C. **Eprontia*** will be approved based on **ONE** of the following criteria:

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1. **BOTH** of the following:

   a. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

      (1) age
      (2) oral/motor difficulties
      (3) dysphagia

-AND-

   b. Patient has a history of trial and failure, intolerance or contraindication to topiramate sprinkles (Topamax Sprinkle)

-OR-

2. Patient utilizes a feeding tube for medication administration

Authorization will be issued for 12 months

D. **Valsartan oral solution** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

-AND-

2. Patient has a history of trial and failure, intolerance or contraindication to one of the following:

   a. enalapril oral solution (generic Epaned)
   b. Qbrelis (lisinopril) oral solution

Authorization will be issued for 12 months

E. **Xelstrym** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

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-AND-

2. Patient has a history of trial and failure, intolerance or contraindication to **both** of the following:

   a. amphetamine/dextroamphetamine extended-release (generic Adderall XR) opened and sprinkled on soft food (e.g. applesauce)

   b. **One** of the following:

      (1) methylphenidate extended-release capsules (generic Metadate CD, generic Ritalin LA) opened and sprinkled on soft food (e.g. applesauce)
      (2) dexmethylphenidate extended-release (generic Focalin XR) opened and sprinkled on soft food (e.g. applesauce)

Authorization will be issued for 12 months

F. **Sympazan** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

-AND-

2. Patient has a history of trial and failure or intolerance to clobazam oral suspension (generic Onfi)

Authorization will be issued for 12 months

G. **Imkeldi** will be approved based on **ONE** of the following:

1. Patient is less than 19 years of age

-OR-

2. **BOTH** of the following:

   a. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

      (1) age
      (2) oral/motor difficulties
      (3) dysphagia
      (4) utilizes feeding tube for medication administration

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-AND-

b. Patient is unable to achieve desired dose by dissolving imatinib 100 mg or 400 mg tablets in water or apple juice

Authorization will be issued for 12 months

H. **Vyscoxa** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

-AND-

2. Patient is unable to achieve desired dose by opening celecoxib capsules and adding to applesauce

Authorization will be issued for 12 months

I. **Subvenite** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

-AND-

2. Patient is unable to achieve desired dose with lamotrigine chewable tablet

Authorization will be issued for 12 months

J. **Javadin** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

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-AND-

2. Patient has a history of trial and failure or intolerance to clonidine patch (generic Catapress)

Authorization will be issued for 12 months

K. **Katerzia* and Sdamlo*** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

-AND-

2. Patient has a history of trial and failure or intolerance to Norliqva

Authorization will be issued for 12 months

L. **Ontralfy** will be approved based on **BOTH** of the following:

1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

   a. age
   b. oral/motor difficulties
   c. dysphagia
   d. utilizes feeding tube for medication administration

-AND-

2. Patient has a history of trial and failure or intolerance to baclofen oral solution

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Typically excluded from coverage.
^Brand only typically excluded from coverage.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10)

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and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Epaned [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; July 2020.
2. Flolipid [package insert]. Brooksville, FL: Salerno Pharmaceuticals LP; June 2020.
3. Nexium [package insert]. Wilmington, DE: AstraZeneca; July 2023.
4. Prevacid SoluTab [package insert]. Deerfield, IL: Takeda Pharmaceuticals America; August 2023.
5. Qbrelis [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; April 2023.
6. Sotylize [package insert]. Woburn, MA: Azurity Pharmaceuticals, LLC.; January 2024.
7. Syndros [package insert]. Chandler, AZ: Benuvia Therapeutics Inc; September 2022.
8. Xatmep [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; September 2020.
9. Zegerid [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; July 2023.
10. Carospir [package insert] Farmville, NC: CMP Pharma, Inc.; August 2023.
11. Tiglutik [package insert]. Berwyn, PA: ITF Pharma, Inc.; March 2020.
12. Naprosyn [package insert]. Atlanta, GA: Athena Bioscience LLC.; April 2021.
13. Tirosint-Sol [package insert]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; July 2024.
14. Katerzia [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; April 2023.
15. Prograf Granules [package insert]. Northbrook, IL: Astellas Pharma US, Inc; August 2023.
16. Ezallor Sprinkle [package insert]. Cranbury, NJ: Sun Pharmaceutical, Inc.; August 2023.
17. Alkindi Sprinkle [package insert]. Baden-Wuerttemberg, Germany: Glatt Pharmaceuticals Services GmbH & Co; December 2024.
18. Indocin suspension [package insert]. Wayne, PA: Zyla Life Sciences US Inc; April 2021.
19. Indocin suppository [package insert]. Wayne, PA: Zyla Life Sciences US Inc; March 2021.
20. Renvela [package insert]. Cambridge, MA: Genzyme Corporation; March 2023.
21. Chlorpromazine [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; June 2021.
22. Fleqsuvy [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; February 2023.
23. Eprontia [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; May 2023.
24. Meloxicam [package insert]. Birmingham, AL: Avondale Pharmaceuticals, LLC; April 2022.
25. Valsartan [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; September 2023.
26. Norliqva [package insert]. Farmville, NC: CMP Pharma, Inc; February 2022.
27. Zonisade [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; March 2023.
28. Ermeza [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; April 2022.
29. Pradaxa oral pellets [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceutical, Inc; November 2023.
30. Xelstrym [package insert]. Miami, FL: Noven Therapeutics, LLC; November 2023.
31. Atorvaliq [package insert]. Farmville, NC: CMP Pharma, Inc.; April 2024.
32. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics; March 2024.
33. Ozobax DS [package insert]. Athens, GA: Metacel Pharmaceuticals, LCC; October 2023.
34. Jylamvo [package insert]. Cambridge, MA: Shorla Oncology Inc; October 2024.
35. Imkeldi [package insert]. Cambridge, MA: Shorla Oncology Inc; November 2024.
36. Inzirqo [package insert]. Baudette, MN: ANI Pharmaceutical, Inc; February 2025.
37. Xromi [package insert]. Franklin, TN: Nova Laboratories, Ltd; December 2024.
38. Raldesy TM [package insert]. Parsippany, NJ: Validus Pharmaceuticals LLC; March 2025.
39. Arbli [package insert]. Commach, NY: Scienture LLC; March 2025.
40. Khindivi [package insert]. Deer Park, IL: Eton Pharmaceuticals, Inc; June 2025.
41. Lopressor [package insert]. Parsippany, NJ: Validus Pharmaceuticals, LLC; April 2025.

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42. Brynovin [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc; January 2025.
43. Vyscoxa [package insert]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC: Jul; 2025.
44. Subvenite [package insert]. Lisle, IL: OWP Pharmaceuticals, Inc.;September 2025.
45. Desmoda [package insert]. Deer Park, IL: Eton Pharmaceuticals, Inc.; March 2026.
46. Sdamlo [package insert]. Brielle, NJ: Pangea Pharmaceuticals, LLC; February 2026.
47. Javadin [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc; September 2025.
48. Ontralfy [package insert]. Greenville, SC: Rosemount Pharmaceuticals, LLC; September 2025.
49. Atmeksi [package insert]. Greenville, SC: Rosemount Pharmaceuticals, LLC; August 2025.

Program	Prior Authorization/Medical Necessity –Non-Solid Oral and Suppository Dosage Forms
Change Control	
Date	Change
8/2014	New program.
11/2014	Updated PPI criteria to include non-solid dosage forms. Updated to incorporate Epaned. Added Purixan to criteria.
2/2015	Updated background section to remove auto-lookback for Purixan.
4/2015	Sotylize added
1/2016	Zegerid suspension added. Updated criteria to allow for coverage when patient has a feeding tube. Removed reauthorization criteria.
3/2016	Updated criteria for Zegerid to also require step through Nexium suspension and Prevacid SoluTabs. Updated background to remove Zegerid from statement that it will automatically process for patients under age 6.
7/2016	Added Indiana and West Virginia coverage information.
10/2016	Updated with Qbrelis. Added California coverage information.
2/2017	Vanatol LQ added to criteria. State mandate reference language updated.
7/2017	Xatmep added to criteria. Updated reference.
10/2017	Flolipid and Syndros added to criteria.
3/2018	Carospir added to criteria.
11/2018	Tiglutik added to criteria.
3/2019	Naprosyn suspension added to criteria. Updated references.
8/2019	Tirosint-Sol and Katerzia added to criteria. Updated references.
11/2019	Prograf Granules added to criteria.
12/2019	Ezallor Sprinkle added to criteria.
2/2020	Drizalma, Gloperba, Ontralfy, Ozobax and Simvastatin oral suspension (Flolipid authorized generic) added to criteria.
12/2020	Alkindi Sprinkle and Carafate suspension added to criteria.
2/2021	Qdolo added to criteria.
5/2021 - effective 1/1/2022	Indocin suspension and suppository added to criteria.

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10/2021 – effective – 1/1/2022	Exservan added to criteria.
9/2021 – effective 5/1/2022	Renvela powder for suspension added to criteria. Updated references.
1/2022- effective 5/1/2022	Chlorpromazine oral solution added to criteria.
6/2022 – effective 9/1/2022	Fleqsuvy and Eprontia oral suspension added to criteria.
9/2022	Removed Purixan and Vanatol LQ. Added Meloxicam suspension, Lyvispah, Norliqva and Valsartan oral solution to criteria. Updated references.
11/2022	Aspruzyo and Zonisade added to criteria and Drizalma removed. Added requirement for Valsartan oral solution to step through Epaned or Qbrelis.
1/2023	Ermeza added to criteria. Katerzia removed from background section and Norliqva added to allow automatic processing for under 6 years old.
5/2023	Pradaxa oral pellets added to criteria.
7/2023	Updated step one option for Zegerid suspension to the generic for Prevacid SoluTabs. Added Xelstrym to criteria.
9/2023	Atorvaliq added to criteria.
12/2023	Added Sympazan and Ozobax DS to criteria. Removed Gloperba since it is off the market. Updated references.
5/2024	Jylamvo added to criteria.
2/2025	Updated background to note Jylamvo will process automatically for patients under the age of six. Removed Ozobax regular strength and Exservan from criteria as they are no longer on the market.
6/2025	Imkeldi, Inzirqo, Raldesy and Xromi added to criteria.
8/2025	Arbli, Khindivi, Lopressor oral solution, and Tezruly added to criteria.
11/2025	Lyvispah and Qdolo removed as they are off the market. Carafate removed from criteria. Updated to note brand only Epaned, Feqsuvy, Indocin Suspension, Indocin Suppositories and Nexium Suspension are typically excluded. Brynovin added to criteria.
2/2026	Subvenite and Vyscoxa added to criteria.
5/2026	Atmeksi, Desmoda, Javadin, Ontralfy and Sdamlo added to criteria. Criteria for Katerzia updated to include step through Norliqva.

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