

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2040-24
Program	Prior Authorization/Medical Necessity – Non-Solid Oral and Suppository Dosage Forms
Medication	Alkindi Sprinkle (hydrocortisone)*, Carafate (sucralfate) suspension, Carospir (spironolactone), chlorpromazine oral solution, Drizalma Sprinkle (duloxetine) Epaned (enalapril), Exservan (riluzole)*, Ezallor Sprinkle (rosuvastatin), Flolipid (simvastatin), Gloperba (colchicine), Indocin (indomethacin) suspension, Indocin (indomethacin) suppository, Katerzia (amlodipine), Naprosyn* (naproxen) suspension, Nexium for suspension (esomeprazole), Ozobax (baclofen), Prevacid SoluTab (lansoprazole), Prograf Granules (tacrolimus), Purixan (mercaptopurine), Qbrelis (lisinopril), Qdolo (tramadol)*, Renvela (sevelamer carbonate) powder for suspension, Sotylize (sotalol), Syndros (dronabinol), Tiglutik (riluzole), Tirosint-Sol (levothyroxine), Vanatol LQ (butalbital, acetaminophen and caffeine), Xatmep (methotrexate), Zegerid for suspension (omeprazole and sodium bicarbonate)*
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
Effective Date	5/1/2022; Oxford only: 5/1/2022

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, Carafate suspension, Carospir, chlorpromazine oral solution, Drizalma Sprinkle, Epaned, Flolipid, Indocin, Katerzia, Naprosyn suspension, Nexium suspension, Ozobax, Prevacid SoluTab, Prograf Granules, Qbrelis, Simvastatin oral suspension (Flolid authorized generic) Sotylize, Tirosint-Sol and Xatmep.

2. Coverage Criteria^a:

<p>A. Alkindi Sprinkle, Carafate suspension, Carospir, chlorpromazine oral solution, Drizalma Sprinkle, Epaned, Exservan, Ezallor Sprinkle, Flolipid, Gloperba, Indocin suspension, Indocin suppository, Katerzia, Naprosyn suspension, Nexium suspension, Ozobax, Prevacid SoluTabs, Prograf Granules, Purixan, Qbrelis, Qdolo, Renvela powder for suspension, Simvastatin oral suspension (Flolid</p>
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authorized generic) Sotylize, Syndros, Tiglutik, Tirosint-Sol, Vanatol LQ and Xatmep 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

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
 - b. Prevacid SoluTabs

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.

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) 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; March 2020.
2. Flolipid [package insert]. Brooksville, FL: Salerno Pharmaceuticals LP; June 2020.
3. Nexium [package insert]. Wilmington, DE: AstraZeneca; November 2020.
4. Prevacid SoluTab [package insert]. Deerfield, IL: Takeda Pharmaceuticals America; November 2020.
5. Purixan [package insert]. Franklin, TN: Rare Disease Therapeutics, Inc.; April 2020.
6. Qbrexelis [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; March 2020.
7. Sotylyze [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.; July 2015.
8. Syndros [package insert]. Chandler, AZ: Benuvia Therapeutics Inc; July 2020.
9. Vanatol LQ [package insert]. Arlington, TX: GM Pharmaceuticals, Inc.; July 2017.
10. Xatmep [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; March 2020.
11. Zegerid [package insert]. Raleigh, NC: Salix Pharmaceuticals, Inc.; September 2019.
12. Carospir [package insert] Farmville, NC: CMP Pharma, Inc.; June 2020.
13. Tiglutik [package insert]. Berwyn, PA: ITF Pharma, Inc.; December 2019.
14. Naprosyn [package insert]. Atlanta, GA: Athena Bioscience LLC.; July 2019.
15. Tirosint-Sol [package insert]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; January 2021.
16. Katerzia [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; March 2020.
17. Prograf [package insert]. Northbrook, IL: Astellas Pharma US, Inc; July 2019.
18. Ezallor Sprinkle [package insert]. Cranbury, NJ: Sun Pharmaceutical, Inc.; October 2020.
19. Gloperba [package insert]. Alpharetta, GA: Avion Pharmaceuticals, LLC.; February 2019.
20. Ozobax [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
21. Drizalma Sprinkle [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc; July 2020.
22. Carafate [package insert]. Madison, NJ: Allergan USA, Inc; June 2018.
23. Alkindi Sprinkle [package insert]. Baden-Wuerttemberg, Germany: Glatt Pharmaceuticals Services GmbH & Co; October 2020.
24. Qdolo [package insert]. Athens, GA: Athena Bioscience, LLC; September 2020.

25. Indocin suspension [package insert]. Wayne, PA: Zyla Life Sciences US Inc; December 2019.
26. Indocin suppository [package insert]. Wayne, PA: Zyla Life Sciences US Inc; September 2019.
27. Renvela [package insert]. Cambridge, MA: Genzyme Corporation; May 2021.
28. Exservan [package insert]. Warren, NJ: Aquestive Therapeutics; April 2020.
29. Chlorpromazine [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; June 2021.

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 Qbreliis. 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, 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.
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.