



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2040-13
Program	Prior Authorization/Medical Necessity – Non-Solid Oral Dosage Forms
Medication	Carospir (spironolactone), Epaned (enalapril), Flolipid (simvastatin), Nexium for suspension (esomeprazole), Prevacid SoluTab (lansoprazole), Purixan (mercaptopurine), Qbrelis (lisinopril), Sotylize (sotalol), Syndros (dronabinol), Tiglutik (riluzole), 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
Effective Date	2/1/2019; Oxford only: 2/1/2019

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 Carospir, Epaned, Flolipid, Nexium suspension, Prevacid SoluTab, Qbrelis, Sotylize and Xatmep.

2. Coverage Criteria^a:

<p>A. Carospir, Epaned, Flolipid, Nexium suspension, Prevacid SoluTabs, Purixan, Qbrelis, Sotylize, Syndros, Tiglutik, Vanatol LQ and Xatmep will be approved based on <u>ONE</u> of the following criteria:</p> <ol style="list-style-type: none">1. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:<ol style="list-style-type: none">a. ageb. oral/motor difficultiesc. dysphagia <p style="text-align: center;">-OR-</p> <ol style="list-style-type: none">2. Patient utilizes a feeding tube for medication administration <p>B. Zegerid suspension* will be approved based on <u>BOTH</u> of the following criteria:</p> <ol style="list-style-type: none">1. <u>ONE</u> 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 prescribing information. Silvergate Pharmaceuticals, Inc. Greenwood Village, CO. September 2016.
2. Flolipid prescribing information. Salerno Pharmaceuticals LP. Brooksville, FL. July 2017.
3. Nexium prescribing information. AstraZeneca, Wilmington, DE. December 2016.

4. Prevacid SoluTab prescribing information. Takeda Pharmaceuticals America. Deerfield, IL. October 2016.
5. Purixan prescribing information. Rare Disease Therapeutics, Inc. Franklin TN. December 2014.
6. Qbrelis prescribing information. Silvergate Pharmaceuticals, Inc. Greenwood Village, CO. July 2016.
7. Sotylize prescribing information. Arbor Pharmaceuticals, LLC. Atlanta, GA. July 2015.
8. Syndros prescribing information. Insys Therapeutics, Inc. Chandler, AZ. May 2017.
9. Vanatol LQ prescribing information. GM Pharmaceuticals, Inc. Arlington, TX. March 2015.
10. Xatmep prescribing information. Silvergate Pharmaceutical, Inc. Greenwood Village, CO. April 2017.
11. Zegerid prescribing information. Salix Pharmaceuticals, Inc. Raleigh NC. October 2016.
12. Carospir prescribing information. CMP Pharma, Inc. Farmville, NC. August 2017.
13. Tiglutik prescribing information. ITF Pharma, Inc. Berwyn, PA. September 2018.

Program	Prior Authorization/Medical Necessity –Non-Solid Dosage Form
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.