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## DRUG POLICY

# Non-Solid Oral Dosage Forms

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Non-Solid Oral Dosage Forms policy is to ensure the appropriate use of cost-effective, clinically appropriate, preferred lower cost alternatives over other high-cost non-solid oral dosage form agents. Coverage criteria outlined below are for patients unable to ingest solid oral dosage forms. Prior authorization is not required for aripiprazole oral solution, Baraclude, CaroSpir, citalopram, Epaned, Elyxyb, Eprontia, Fleqsuvy, Gloperba, Indocin oral suspension, Katerzia, brand and generic Lyrica oral solution, Lyvispah, brand and generic Namenda oral solution, brand and generic Naprosyn (naproxen) oral suspension, Norliqva (amlodipine) oral solution, nortriptyline oral solution, Ozobax, brand and generic Paxil (paroxetine) oral suspension, Purixan, Qbrelis, brand and generic Rapamune oral solution, brand and generic Riomet IR and ER, brand and generic Risperdal oral solution and orally disintegrating tablet, simvastatin 20mg/5mL oral suspension, Sotylize, Syndros, Xatmep, valsartan oral solution, Vesicare LS, Zonisade oral suspension, and Dificid oral suspension if the patient is under 7 years of age. Prior authorization is not required for brand and generic Cuvposa if the patient is under 17 years of age. Prior authorization for Aspruzyo Sprinkles, Drizalma Sprinkles, Dartisla orally disintegrating tablet, Myrbetriq Granules, and Alkindi Sprinkles is required for all patients.

### POLICY

#### Criteria for Approval

- A. Aripiprazole oral solution, Baraclude oral solution (entecavir), CaroSpir (spironolactone), citalopram oral solution, Epaned (enalapril), FloLipid (simvastatin), Gloperba (colchicine), Indocin (indomethacin) oral suspension, Katerzia oral suspension (amlodipine), brand and generic Lyrica oral solution (pregabalin), brand and generic Namenda (memantine) oral solution, brand and generic Naprosyn (naproxen) oral suspension, Norliqva (amlodipine) oral solution, nortriptyline oral solution, brand and

generic Paxil (paroxetine) oral suspension, Purixan (mercaptopurine), Qbrelis (lisinopril), brand and generic Rapamune (sirolimus) oral solution, brand and generic Riomet IR and ER (metformin), brand and generic Risperdal (risperidone) oral solution and orally disintegrating tablet (ODT), simvastatin 20mg/5mL oral suspension, Sotylize (sotalol), Syndros (dronabinol), valsartan oral solution, Zonisade oral suspension, and Xatmep (methotrexate) may be considered **medically necessary** when the patient is unable to swallow the oral solid dosage forms (e.g., an oral tablet or capsule) due to one of the following:

- a) Age
- b) Dysphagia
- c) Oral/Motor difficulties
- d) Medications are administered through a feeding tube

Approval will be for **12 months**.

B. Drizalma Sprinkles (duloxetine) may be considered **medically necessary** when the patient is unable to swallow the oral solid dosage form, generic Cymbalta (duloxetine) delayed release capsules, due to one of the following:

- a) Dysphagia
- b) Oral/Motor difficulties
- c) Medications are administered through a feeding tube

Approval will be for **12 months**.

C. Aspruzyo Sprinkles (ranolazine) may be considered **medically necessary** when the patient is unable to swallow the oral solid dosage form, generic Ranexa (ranolazine) extended-release tablets, due to one of the following:

- a) Dysphagia
- b) Oral/Motor difficulties
- c) Medications are administered through a feeding tube

Approval will be for **12 months**.

D. Eprontia (topiramate) may be considered **medically necessary** when the patient has tried and failed the alternative, topiramate sprinkle capsules when opened and sprinkled onto soft food or liquid or the patient is unable due to one of the following:

- a) Age
- b) Dysphagia
- c) Oral/Motor difficulties
- d) Medications are administered through a feeding tube

Approval will be for **12 months**.

E. Elyxyb (celecoxib) may be considered **medically necessary** when the patient has tried and failed the alternative, celecoxib capsules when opened and sprinkled onto soft food or liquid or the patient is unable due to one of the following:

- a) Age
- b) Dysphagia
- c) Oral/Motor difficulties
- d) Medications are administered through a feeding tube

Approval will be for **12 months**.

- F. Fleqsuvy (baclofen oral suspension) Lyvispah (baclofen oral granules) and Ozobax (baclofen oral solution) may be considered **medically necessary** when the following criteria is met:
- a) The requested drug is being used for the treatment of spasticity resulting from multiple sclerosis.
  - b) The patient has tried and failed swallowing baclofen tablets when crushed and sprinkled on soft food or liquid OR are the patient is unable to swallow baclofen tablets when crushed and sprinkled on soft food or liquid due to one of the following:
    - Age
    - Dysphagia
    - Oral/Motor difficulties
    - Medications are administered through a feeding tube
  - c) The dose requested is less than or equal to 80 mg per day
  - d) Ozobax only: The dose requested is less than 80 mg per day OR a lower dosage has been ineffective and additional quantities (up to 200 mg per day\*) are required to treat/manage the patient's condition

Approval will be for **12 months**.

\*Coverage for additional quantities will not exceed 200 mg per day as higher dosage has not been demonstrated to be safe and effective

- G. Brand and generic Cuvposa (glycopyrrolate) may be considered **medically necessary** when the following criteria is met:
- a) Must have a neurological condition associated with chronic, severe drooling (sialorrhea)
  - b) The patient is unable to swallow the oral tablet formulation of glycopyrrolate due to one of the following:
    - Age
    - Dysphagia
    - Oral/Motor difficulties
    - Medications are administered through a feeding tube

Approval will be for **12 months**.

- H. Vesicare LS (solifenacin succinate) oral suspension may be considered **medically necessary** when the following criteria is met:
- a) The patient is 2 years of age or older
  - b) The patient has neurogenic detrusor overactivity as confirmed by urodynamic studies (UDS)
  - c) The patient is unable to swallow the oral tablet formulation of solifenacin succinate due to one of the following:
    - Age
    - Dysphagia
    - Oral/Motor difficulties
    - Medications are administered through a feeding tube
  - d) The dose requested is less than or equal to 10 mg per day

Approval will be for **12 months**.

\*Coverage for additional quantities will not exceed 10 mg per day as higher dosage has not been demonstrated to be safe and effective

- I. Myrbetriq Granules (mirabegron) for extended-release oral suspension may be considered **medically necessary** when the following criteria is met:
- a) The patient is 3 years of age or older
  - b) The patient has neurogenic detrusor overactivity as confirmed by urodynamic studies (UDS)
  - c) The patient is unable to swallow the oral tablet formulation of Myrbetriq (mirabegron) due to one of the following:
    - Age
    - Dysphagia
    - Oral/Motor difficulties
    - Medications are administered through a feeding tube
  - d) The dose requested is less than or equal to 80 mg (10 mL) per day

Approval will be for **12 months**

- J. Dartisla (glycopyrrolate) ODT may be considered **medically necessary** when the following criteria is met:
- e) The patient is 18 years of age or older
  - f) The patient has a diagnosis of peptic ulcer disease
  - g) Dartisla ODT will be used as an adjunct to treatment of peptic ulcer disease (e.g., PPI therapy)
  - h) The patient is unable to swallow the oral tablet formulation of glycopyrrolate due to one of the following:
    - Age
    - Dysphagia
    - Oral/Motor difficulties
    - Medications are administered through a feeding tube

Approval will be for **3 months**

- K. Alkindi Sprinkles (hydrocortisone) may be considered **medically necessary** when the following criteria is met:
- a) The patient has adrenocortical insufficiency
  - b) The patient is 17 years of age or younger
  - a. The patient is unable to swallow the oral tablet formulation of hydrocortisone due to one of the following:
    - Age
    - Dysphagia
    - Oral/Motor difficulties

Approval will be for **12 months.**

- L. Dificid (fidaxomicin) oral suspension may be considered **medically necessary** when the following criteria is met:
- a) The requested drug is being used to treat *Clostridioides difficile*-Associated Diarrhea (CDAD)
  - b) The patient has proven or strongly suspected *Clostridioides difficile* (*C. difficile*) infection
  - c) The patient is 6 months of age or older
  - d) The patient's weight is greater than or equal to 4 kg
  - e) The dosing regimen requested is less than or equal to 200 mg twice daily for 10 days
  - f) The patient is unable to swallow the oral tablet formulation of Dificid (fidaxomicin) due to one of the following:
    - Age
    - Dysphagia

- Oral/Motor difficulties
- Medications are administered through a feeding tube

Approval will be for **30 days**.

\*Coverage for indications other than CDAD are considered not medically necessary and are not covered as Difucid has not been studied for the treatment of infections other than CDAD. Difucid should only be used for the treatment of CDAD.

The aforementioned drugs are considered **not medically necessary** for patients who do not meet the criteria set forth above.

#### Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### Quantity limits apply:

Aripiprazole 1 mg/mL oral solution: 900 mL per 30 days  
 Aspruzyo sprinkle 500 mg and 1000 mg sachet: 2 sachets per day  
 Baraclude (entecavir) 0.05 mg/mL oral solution: 630 mL per 30 days  
 CaroSpir (spironolactone): 600 mL per 30 days  
 Citalopram 10 mg/5 mL oral solution: 600 mL per 30 days  
 Cuvposa (glycopyrrolate): 1350 mL per 30 days  
 Dartisla (glycopyrrolate) ODT: 120 tablets per 30 days  
 Difucid (fidaxomicin) oral suspension: 300 mL per 30 days  
 Drizalma Sprinkles (duloxetine) 20mg, 30mg: 30 capsules per 30 days  
 Drizalma Sprinkles (duloxetine) 40mg, 60mg: 60 capsules per 30 days  
 Epaned (enalapril): 1200 mL per 30 days  
 Eprontia (topiramate): 480 mL per 30 days  
 Elyxyb (Celecoxib): 144 mL per 30 days  
 Gloperba (colchicine): 600 mL per 30 days  
 Qbrelis (lisinopril): 1200 mL per 30 days  
 FloLipid (simvastatin) 20mg/5mL oral suspension: 300 mL per 30 days  
 Simvastatin 20mg/5mL oral suspension: 300 mL per 30 days  
 FloLipid (simvastatin) 40mg/5mL oral suspension: 150 mL per 30 days  
 Indocin (indomethacin) oral suspension: 1200 mL per 30 days  
 Katerzia (amlodipine): 300 mL per 30 days  
 Lyrica (pregabalin) oral solution: 900 mL per 30 days  
 Myrbetriq (mirabegron) granules for suspension 300 mL per 30 days  
 Lyvispah (baclofen) oral granules: 4 packets per day  
 Namenda (memantine) oral solution: 300 mL per 30 days  
 Nortriptyline oral solution: 2400 mL per 30 days  
 Norliqva (amlodipine) oral solution: 300 mL per 30 days  
 Ozobax (baclofen): 6,000 mL per 30 days  
 Fleqsuvy (baclofen) oral suspension: 480 mL per 30 days  
 Paxil (paroxetine) oral suspension: 900 mL per 30 days  
 Sotylize (sotalol): 1920 mL per 30 days  
 Rapamune (sirolimus) oral solution: 1200 mL per 30 days  
 Riomet IR and ER (metformin): 765 mL per 30 days  
 Risperdal (risperidone) oral solution: 480 mL per 30 days  
 Valsartan oral solution: 80 mL per 30 days  
 Vesicare LS (solifenacin succinate): 300 mL per 30 days

Zonisade (zonisamide) oral suspension: 900 mL per 30 days

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- Code(s), if applicable

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## POLICY HISTORY

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