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, Corlanor oral solution, Epaned, Gloperba, Indocin oral suspension, Katerzia, brand and generic Lyrica oral solution, brand and generic Namenda oral solution, brand and generic Naprosyn (naproxen) oral suspension, nortriptyline oral solution, Ozobax, Purixan, Qbrelis, brand and generic Rapamune oral solution, brand and generic Riomet IR and ER, brand and generic Risperdal oral solution and oral disintegrating tablet, simvastatin 20mg/5mL oral suspension, Sotylize, Syndros, Xatmep, Vesicare LS, and Dificid oral suspension if the patient is under 7 years of age. Prior authorization is not required for Cuvposa if the patient is under 17 years of age. Prior authorization for Drizalma Sprinkles 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, Corlanor oral solution (ivabradine), 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, nortriptyline oral solution, 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 oral disintegrating

tablet (ODT), simvastatin 20mg/5mL oral suspension, Sotylize (sotalol), Syndros (dronabinol), 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. Ozobax (baclofen) may be considered **medically necessary** when the following criteria is met:

a) 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
b) 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

D. 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**.

E. 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

F. 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.**

G. 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 Dificid has not been studied for the treatment of infections other than CDAD. Dificid should only be used for the treatment of CDAD.

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
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
Corlanor (ivabradine) oral solution: 450 mL per 30 days
Cuvposa (glycopyrrolate): 1350 mL per 30 days
Dificid (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
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
Namenda (memantine) oral solution: 300 mL per 30 days
Nortriptyline oral solution: 2400 mL per 30 days
Ozobax (baclofen): 6,000 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
Vesicare LS (solifenacin succinate): 300 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

REFERENCES

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POLICY HISTORY

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