BlueCross BlueShield
Federal Employee Program

PDE5 INHIBITOR POWDERS
Sildenafil powder, Tadalafil powder

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following

Sildenafil and Tadalafil Powders

1. Pulmonary arterial hypertension (PAH) - WHO Group I
    a. NYHA functional classification of physical activity - Class II or III
    b. Prescribed by or recommended by a cardiologist or pulmonologist
    c. Prescriber agrees to counsel and evaluate the patient for sudden loss of vision or hearing associated with this medication
    d. **NO** concurrent therapy with **ALL** of the following:
        i. Any nitrates (in any form)
        ii. Another PDE-5 inhibitor
        iii. Guanylate cyclase (GC) stimulators
        iv. Alpha blockers
    e. **Tadalafil powder only**: **NO** severe hepatic impairment (Child-Pugh Class C) **AND NO** severe renal impairment (creatinine clearance <30 mL/min)
    f. The requested **oral** dose does not exceed 20mg / unit

Sildenafil Powder Only

1. Raynaud's syndrome
    a. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following:
        i. Calcium channel blockers
        ii. Alpha adrenergic receptor blockers
        iii. Angiotensin II receptor antagonist
    b. Prescriber agrees to counsel and evaluate the patient for sudden loss of vision or hearing associated with this medication
    c. **NO** concurrent therapy with **ALL** of the following:
        i. Any nitrates (in any form)
        ii. Another PDE-5 inhibitor
        iii. Guanylate cyclase (GC) stimulators
        iv. Alpha blockers

d. The requested **oral** dose does not exceed 20mg / unit

Tadalafil Powder Only

1. Benign prostatic hyperplasia / hypertrophy (BPH)
    a. Age 18 years of age or older
    b. Actively symptomatic including **ONE or MORE** of the following:
        i. Dribbling at the end of urinating
        ii. Inability to urinate (urinary retention)
        iii. Incomplete emptying of bladder
        iv. Incontinence
        v. Nocturia - needing to urinate two or more times per night
        vi. Pain with urination or bloody urine
        vii. Slowed or delayed start of the urinary stream
        viii. Straining to urinate
        ix. Strong and sudden urge to urinate
        x. Weak urine stream
    c. Treatment failure or clinically significant adverse reaction to **ONE** of
    the following:
        i. Alpha blocker
        ii. 5-alpha reductase inhibitor
    d. **NO** concurrent therapy with **ALL** of the following:
        i. Any nitrates (in any form)
        ii. Another PDE-5 inhibitor
        iii. Guanylate cyclase (GC) stimulators
    e. The requested **oral** dose does not exceed 5 mg / unit

AND ALL of the following for **ALL** powders and **ALL** indications:

1. **NOT** being used for erectile or sexual dysfunction
2. The requested strength is **NOT** commercially available
3. The requested dosage form is **NOT** being used topically

Prior - Approval Limits

Duration 2 years for PAH and Raynaud's syndrome
12 months for BPH

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PDE5 INHIBITOR POWDERS
Sildenafil powder, Tadalafil powder

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following

Sildenafil and Tadalafil Powders

1. Pulmonary arterial hypertension (PAH) - WHO Group I
    a. Symptoms have improved or stabilized
    b. Prescriber agrees to counsel and evaluate the patient for sudden loss of vision or hearing associated with this medication
    c. **NO** concurrent therapy with **ALL** of the following:
        i. Any nitrates (in any form)
        ii. Another PDE-5 inhibitor
        iii. Guanylate cyclase (GC) stimulators
        iv. Alpha blockers
    d. **Tadalafil powder only**: **NO** severe hepatic impairment (Child-Pugh Class C) **AND NO** severe renal impairment (creatinine clearance <30 mL/min)
    e. The requested **oral** dose does not exceed 20mg / unit

Sildenafil Powder Only

1. Raynaud's syndrome
    a. Symptoms have improved or stabilized
    b. Prescriber agrees to counsel and evaluate the patient for sudden loss of vision or hearing associated with this medication
    c. **NO** concurrent therapy with **ALL** of the following:
        i. Any nitrates (in any form)
        ii. Another PDE-5 inhibitor
        iii. Guanylate cyclase (GC) stimulators
        iv. Alpha blockers
    d. The requested **oral** dose does not exceed 20mg / unit

Tadalafil Powder Only

1. Benign prostatic hyperplasia / hypertrophy (BPH)
    a. Age 18 years of age or older
    b. Improvement in urinary symptoms
    c. **NO** concurrent therapy with **ALL** of the following:

i. Any nitrates (in any form)
ii. Another PDE-5 inhibitor
iii. Guanylate cyclase (GC) stimulators

d. The requested **oral** dose does not exceed 5 mg / unit

AND ALL of the following for **ALL** powders and **ALL** indications:

1. **NOT** being used for erectile or sexual dysfunction
2. The requested strength is **NOT** commercially available
3. The requested dosage form is **NOT** being used topically

Prior - Approval *Renewal* Limits

Same as above