AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: (select drug below)

❑ **Daraprim®** (pyrimethamine)	❑ **pyrimethamine**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Quantity Limits (for any indication):

- 90 tablets monthly [3 (25mg) tablets daily]
- **Children:** 1 to 2mg/kg once daily

Length of Authorization:

- **Initial Treatment: 6 weeks**
- **Continuation of therapy: up to 6 months {unless otherwise indicated on form}**

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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- ❑ **For approval of BRAND NAME Daraprim for all diagnoses:** Member must have had trial and intolerable life-endangering adverse event with generic pyrimethamine tablets **(progress notes with descriptions of adverse event along with completed MedWatch form must be submitted)**

❑ Toxoplasmosis - Primary Prophylaxis

- ❑ Member must have a diagnosis of HIV/AIDS
- ❑ Member must have a CD4 count < 100 cells/mm3
- ❑ Member must test positive for Toxoplasmosis gondii IgG antibodies
- ❑ **Documented intolerance** to recommended **first line agent TMP-SMX** (trimethoprim-sulfamethoxazole); and TMP-SMX **desensitization** has been attempted **(Description of specific intolerance to TMP-SMX, along with completed MedWatch form must be submitted and trial of desensitization must be documented in progress notes and submitted with this request)**

❑ Toxoplasmosis - Treatment

- ❑ Diagnosis made by an infectious disease specialist, neurologist, or HIV specialist
- ❑ Member with a diagnosis of HIV/AIDS must have a CD4 count of < 100 cells/mm3
- ❑ Clinical syndrome of headache, fever, and neurological symptoms (confusion, motor weakness) must be present
- ❑ Submission of positive serum testing for Toxoplasmosis gondii IgG antibodies
- ❑ Submission of clinical documentation identifying one or more mass lesions by CT or MRI

❑ Toxoplasmosis - Chronic Maintenance Therapy

- ❑ Member has completed at least six weeks of active treatment for AIDS-related toxoplasmosis **(Pharmacy Paid Claims will be reviewed)**
- ❑ CT scan or MRI documents improvement in ring-enhancing lesions prior to initiating maintenance therapy
- ❑ Member has documented improvement in clinical symptoms
- ❑ **IF RESTARTING CHRONIC MAINTENANCE THERAPY:** please submit clinical laboratory results documenting patient's CD4 count has decreased < 200 cells/µL

❑ Pneumocystis Pneumonia (PCP) in HIV Infected Members – Primary Prophylaxis

- ❑ Member must have a diagnosis of HIV/AIDS and medication is being prescribed for prophylaxis of pneumocystis pneumonia
- ❑ Member must have a CD4 count of < 200 cells/mm3 or CD4 count percentage of <14%
- ❑ Member has intolerance to **ALL** of the following drug regimens **(progress notes with descriptions of specific intolerances to all medications along with completed MedWatch forms must be submitted):**

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- ❑ Single-strength or double-strength trimethoprim-sulfamethoxazole (TMP-SMX) and TMP-SMX reintroduction/desensitization has been attempted OR member had a life-threatening adverse reaction to TMP-SMX (i.e. possible or definite Stevens-Johnson syndrome or toxic epidermal necrolysis). Please note that as many as 70% of patients can tolerate reinstitution of TMP-SMX therapy per guidelines
- ❑ dapsone
- ❑ atovaquone

❑ Pneumocystis Pneumonia (PCP) in HIV Infected Members – Secondary Prophylaxis

- ❑ Member must have a diagnosis of HIV/AIDS and has received successful treatment for pneumocystis pneumonia infection
- ❑ Member must have a CD4 count of < 200 cells/mm3 or CD4 count percentage of <14%
- ❑ Member has intolerance to **ALL** of the following drug regimens **(progress notes with descriptions of specific intolerances to all medications along with completed MedWatch forms must be submitted)**
  - ❑ Single-strength or double-strength trimethoprim-sulfamethoxazole (TMP-SMX) and TMP-SMX reintroduction/desensitization has been attempted OR member had a life-threatening adverse reaction to TMP-SMX (i.e. possible or definite Stevens-Johnson syndrome or toxic epidermal necrolysis). Please note that as many as 70% of patients can tolerate reinstitution of TMP-SMX therapy per guidelines
  - ❑ dapsone
  - ❑ atovaquone

❑ For Opportunistic Infections in Children

❑ Secondary Prophylaxis or Treatment for Cystoisoporiasis

- ❑ Exposure to HIV OR diagnosis of HIV
- ❑ Documented intolerance/failure to **TMP-SMX** (trimethoprim-sulfamethoxazole) at the appropriate dosing

❑ Primary or Secondary Prophylaxis of Pneumocystis jirovecii pneumonia (PCP)

- ❑ Exposure to HIV OR diagnosis of HIV
- ❑ For children with an HIV diagnosis:
  - ❑ Infants aged <12 months regardless of CD4 count or percentage
  - ❑ Aged 1 to <6 years with CD4 counts <500 cells/mm^3 or CD4 percentage <15%
  - ❑ Aged 6-12 years with CD4 counts <200 cells/mm^3 or CD4 percentage <15%
- ❑ Documented intolerance/failure to **TMP-SMX** (trimethoprim-sulfamethoxazole) at the appropriate dosing
- ❑ Documented intolerance/failure to **dapsone** at the appropriate dosing
- ❑ Documented intolerance/failure to **atovaquone** at the appropriate dosing
- ❑ Documented intolerance/failure to **aerosolized pentamidine** at the appropriate dosing

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❑ Treatment of Toxoplasmosis, Acquired or Congenital Infection

Approval Length – 12 months

- ❑ Therapy will be used in combination with sulfadiazine (or clindamycin if sulfonamide-intolerant) and leucovorin

❑ Prophylaxis of Toxoplasmosis in Hematopoietic Cell Transplantation Recipients

Approval Length – 12 months

- ❑ Therapy will be started after engraftment and administer as long as the patient remains on immunosuppressive therapy.
  - ❑ Date of engraftment: _____
  - ❑ Immunosuppressive therapy: _____
- ❑ Therapy will be used in combination with clindamycin and leucovorin

❑ Primary and Secondary Prophylaxis of Toxoplasmosis

- ❑ Exposure to HIV OR diagnosis of HIVspecialist
- ❑ Toxoplasma-seropositive aged <6 years with CD4 T lymphocyte (CD4) cell percentage <15%
- ❑ Toxoplasma-seropositive aged ≥6 years with CD4 T lymphocyte (CD4) <100 cells/mm^3
- ❑ **FOR primary prophylaxis**: documented intolerance/failure to **TMP-SMX** (trimethoprim-sulfamethoxazole) at the appropriate dosing
- ❑ **FOR secondary prophylaxis,** therapy will be used in combination with sulfadiazine (or clindamycin if sulfonamide-intolerant) and leucovorin

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** 9/15/2016
REVISED/UPDATED: ~~12/12/2016; 8/3/2017; (Reformatted) 9/6/2019;06/24/2020;~~ **10/27/2023**