Commercial/Healthcare Exchange PA Criteria

Effective: August 14th, 2019

Prior Authorization: Pyrimethamine

Products Affected: Daraprim (Pyrimethamine) oral tablets, Pyrimethamine oral tablets

Medication Description: Daraprim is a synthetic antiparasitic agent indicated for the treatment of toxoplasmosis when concurrently used with a sulfonamide

Covered Uses:

1. Toxoplasmosis
2. Pneumocystis Pneumonia (primary and secondary prophylaxis)

Exclusion Criteria:

1. Patients with documented megaloblastic anemia due to folate deficiency
2. Patients with known hypersensitivity to pyrimethamine
3. The use of Daraprim for the treatment or prophylaxis of Malaria is no longer recommended per CDC guidelines for the Treatment of Malaria in the United States.

Required Medical Information:

1. Appropriate Blood work
2. Diagnosis
3. Documentation of previous therapy

Age Restrictions: N/A

Prescriber Restrictions: Compounded Pyrimethamine and Leucovorin are available from the in-network compounding pharmacy Imprimis. **See attached Request Form**

- Compounded pyrimethamine and leucovorin dose forms are less costly than pyrimethamine (Daraprim).
- Use of compounded Pyrimethamine and Leucovorin capsules decreases pill burden. Decreased pill burdens have been linked to improved compliance in some data sets.
- Current guidelines recommend up to 200mg Pyrimethamine PO once followed by 75mg daily for 6 weeks for the treatment of acute toxoplasmosis; prevention and maintenance doses are lower and may be given weekly. Concomitant use of leucovorin is strongly recommended.

Coverage Duration:

Initiation: Two months

Continuation: Therapy beyond two months may be considered medically necessary for the following treatments (chart documentation required):

1. If response is incomplete after 8 weeks; **OR**
2. HIV-infected patients with CD4 < 200 cells/mm^3 and on antiretroviral thearpy

Other Criteria: Approve Daraprim if one of the following criteria are met (1, 2, 3, 4, or 5), chart documentation required:

1. Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

2. Treatment of congenital toxoplasmosis

OR

3. Secondary prophylaxis of toxoplasmic encephalitis

OR

4. **ALL** of the following:

    a. Primary Pneumocystis pneumonia (PCP) prophylaxis in HIV-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

    b. Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

    c. **One** of the following:

        (1) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

        (2) Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

OR

5. **ALL** of the following:

    a. Primary prophylaxis of toxoplasmic encephalitis

    b. Toxoplasma IgG positive

    c. CD4 ≤ 100 cells/mm3 if initiating prophylaxis or if CD4 < 100-200 cells/mm3 if reinstituting prophylaxis

    d. Will be used in combination with dapsone or atovaquone

    e. Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

    f. **One** of the following:

        (1) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

        (2) Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

References:

1. Daraprim full prescribing information. GlaxoSmithKline Research Triangle Park, NC
2. Aidsinfo.nih.gov/guidelines
3. Centers for Disease Control and Prevention. Treatment of Malaria (Guidelines For Clinicians). Accessed January 9, 2018: http://www.cdc.gov/malaria/resources/pdf/clinicalguidance.pdf accessed 7/31/2019

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/14/19
2	Policy Update	Added generic to policy Updated policy name	Policy name Products affected	3/30/2020
3	Annual Review	N/A	N/A	8/4/2020