CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Daraprim (pyrimethamine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Daraprim (pyrimethamine) is an oral folic acid antagonist initially approved by the FDA in 1953. It binds to and reversibly inhibits the protozoal enzyme dihydrofolate reductase, selectively blocking conversion of dihydrofolic acid to its functional form, tetrahydrofolic acid. Daraprim is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

Daraprim (pyrimethamine) will be considered for coverage when the following criteria are met:

Toxoplasmosis

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an infectious disease specialist; AND
2. Member has a diagnosis of congenital toxoplasmosis OR acquired toxoplasmosis confirmed by a positive test for toxoplasmosis gondii IgG antibodies; AND
3. If the request is for acquired toxoplasmosis, member's disease is visceral or symptoms are severe or persistent; AND
4. Daraprim will be used as combination therapy such as leucovorin and sulfadiazine; AND
5. If the request is for a pediatric patient, chart notes document current patient weight.
6. **Dosage allowed/Quantity limit:** Quantity Limit: 90 tablets per 30 days.
   a. Adults: 50 to 75 mg orally once daily
   b. Pediatrics: 1 mg/kg/day orally divided every 12 hours for 2 to 4 days, followed by 0.5 mg/kg/day
   c. Neonates: 2 mg/kg/day orally divided twice daily for 2 days, followed by 1 mg/kg/day orally for 2 to 6 months, then 1 mg/kg/dose orally 3 times weekly

If all the above requirements are met, the medication will be approved for 2 months (12 months for congenital disease).

For **reauthorization**:

1. Chart notes must show that response was incomplete (such as continued symptoms).

If all the above requirements are met, the medication will be approved for an additional 4 months (Medication will not be reauthorized for congenital disease).

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Toxoplasmosis Related to HIV

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an infectious disease specialist, neurologist or HIV specialist; AND
2. Member has a diagnosis of HIV/AIDs; AND
3. Member has documentation of a confirmed positive test for toxoplasmosis gondii IgG antibodies; AND
4. Chart notes provide documentation that member has symptoms (headache, fever, etc.); AND
5. Brain imaging (CT or MRI) demonstrates typical radiographic ring enhancing lesions; AND
6. Chart notes provide documentation of member's current weight; AND
7. Daraprim will be used as combination therapy such as leucovorin and sulfadiazine.
8. **Dosage allowed/Quantity limit:** Quantity Limit: 90 tablets per 30 days.
   a) Adults: 200 mg orally for 1 dose, then 50 mg (less than 60 kg) to 75 mg (60 kg or greater) orally daily.
   b) Pediatrics: 2 mg/kg/dose orally once daily (Max: 50 mg/day) for the first 3 days, followed by 1 mg/kg/dose orally once daily (Max: 25 mg/day).

If all the above requirements are met, the medication will be approved for 2 months.

For **reauthorization**:

1. Chart notes must show at least one of the following:
   a) Member has extensive clinical or radiologic disease; OR
   b) Response was incomplete at 6 weeks (such as continued presence of radiological disease or symptoms)

If all the above requirements are met, the medication will be approved for an additional 6 months.

Chronic Maintenance Therapy of Toxoplasmosis Related to HIV

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an infectious disease specialist, neurologist or HIV specialist; AND
2. Member has a diagnosis of HIV/AIDs; AND
3. Chart notes provide documentation that member has completed 6 weeks of initial therapy for active infection; AND
4. Daraprim will be used as combination therapy such as leucovorin and sulfadiazine.
5. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example, 25 to 50 mg orally once daily.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show the following:
   a. Member has documentation of CD4 count <200 cell/µL at least one of the last six months; OR
   b. Member remains symptomatic; AND
   c. Daraprim will be used as combination therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Toxoplasmosis Prophylaxis Related to HIV

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an infectious disease specialist or HIV specialist; AND
2. Member has a diagnosis of HIV/AIDS; AND
3. Member has documentation of a confirmed positive test for toxoplasmosis gondii IgG antibodies; AND
4. Member has documentation of CD4 count <100 cell/µL; AND
5. Member has tried and failed trimethoprim-sulfamethoxazole; AND
6. Daraprim will be used as combination therapy such as dapsone and leucovorin.
7. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example, 50 to 75 mg orally weekly.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must show BOTH of the following:
   a. Member has documentation of CD4 count <200 cell/µL at least one of the last 3 months; AND
   b. Daraprim will be used as combination therapy.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Pneumocystis Pneumonia (PJP) Prophylaxis Related to HIV

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an infectious disease specialist or HIV specialist; AND
2. Member has a diagnosis of HIV/AIDS; AND
3. Member has documentation of CD4 count <200 cell/µL or CD4 <14% OR chart notes document previous infection with PJP; AND
4. Member has tried and failed trimethoprim-sulfamethoxazole; AND
5. Daraprim will be used as combination therapy such as dapsone and leucovorin.
6. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example, 50 or 75 mg orally once weekly.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must show BOTH of the following:
   a. Member has documentation of CD4 count <200 cell/µL or CD4 <14% at some point in the previous 3 months; AND
   b. Daraprim will be used with dapsone and leucovorin.

NOTE: If the member has acquired PJP with a CD4 count >200 cell/µL while on antiretroviral therapy, prophylaxis should be continued for life.

If all the above requirements are met, the medication will be approved for an additional 6 months.

CareSource considers Daraprim (pyrimethamine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/12/2023	New policy for Daraprim created.

References:

1. Daraprim [prescribing information]. New York, NY: Vyera Pharmaceuticals; August 2017.
2. Centers for Disease Control and Prevention – Toxoplasmosis. Available at: https://www.cdc.gov/parasites/toxoplasmosis/index.html.
3. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/whats-new-guidelines.
4. Maldonado YA, Read JS; COMMITTEE ON INFECTIOUS DISEASES. Diagnosis, Treatment, and Prevention of Congenital Toxoplasmosis in the United States. Pediatrics. 2017;139(2):e20163860. doi:10.1542/peds.2016-3860

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