STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PYRIMETHAMINE

Generic	Brand	HICL	GCN	Medi-Span		Exception/Other
PYRIMETHAMINE	DARAPRIM		42930	GPI-10 (1300004000)		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes**, approve for 6 weeks by GPID or GPI-10. Please enter two authorizations as follows:**
   - **Approve one fill for #8 per day.**
   - **Approve for 6 weeks with a quantity limit of #3 per day.**

   APPROVAL TEXT: Renewal requires that the patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging).

   If no, continue to #2.

2. Is the patient being treated for chronic maintenance of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #3.

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

3. Is the patient being treated for primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The medication is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of or contraindication to Bactrim (SMX/TMP)
   - The patient is positive for *Toxoplasma gondii* IgG
   - The patient has a CD4 count of less than 100 cells/mm(3)

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #4.

4. Does the patient have a diagnosis of congenital toxoplasmosis **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a neonatologist or pediatric infectious disease specialist

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
      4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)
   B. **If you are being treated for acute toxoplasmosis, approval also requires:**
      1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

   (Initial denial text continued on next page)

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV)
   2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
   3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm(3)

E. **If you have congenital toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

   If yes, **approve for 6 weeks by GPID or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

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PYRIMETHAMINE

RENEWAL CRITERIA (CONTINUED)

2. Is the patient being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has a CD4 count of less than 200 cells/mm(3)
   - The patient is currently taking ART (anti-retroviral therapy)

   If yes, **approve for 6 months by GPID or GPI-10 as follows:**
   - **Chronic maintenance of toxoplasmosis: #2 per day.**
   - **Primary prophylaxis of toxoplasmosis: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
      1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)
   C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
      1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
      2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm(3)
      3. You are currently taking ART (anti-retroviral therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PYRIMETHAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daraprim.

REFERENCES

- Daraprim [Prescribing Information]. New York, NY: Vyera Pharmaceuticals LLC., August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 10/15
Client Approval: 02/20
P&T Approval: 01/20