STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		GPI-10 (5250502010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any TWO of the following preferred immunomodulators: Enbrel Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit) then,**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit) then,**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit) then,**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to **BOTH** of the following preferred immunomodulators: Humira and Stelara [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit) then,**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Documentation of the patient's current weight
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient weigh 90 kg or less?

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit) then,**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

   If no, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 kits (each kit contains 2 syringes/vials) per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient meets ONE of the following objective signs of inflammation:
     - C-reactive protein (CRP) levels above the upper limit of normal
     - Sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit) then,**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for non-radiographic axial spondyloarthritis (nr-axSpA) requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

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 named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-rays)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in the digestive system)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Documentation of your current weight
   3. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   4. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   5. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   6. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

G. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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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CERTOLIZUMAB PEGOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

   If yes, continue to #6.
   If no, continue to #7.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

6. Does the patient weigh 90 kg or less?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits** (**each kit contains 2 syringes/vials) per 28 days.**

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   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 named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
      6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-rays)
   B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   C. **If you have psoriatic arthritis (PsA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

E. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

F. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on 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.

RATIONALE

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

REFERENCES

- Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc. March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 05/08
Client Approval: 02/20
P&T Approval: 01/20