cimzia®
(certolizumab pegol)

CODING AND BILLING GUIDE

For the treatment of
active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

This guide summarizes coding and billing information required for the administration of CIMZIA in the healthcare provider and hospital settings for patients with pJIA

INDICATION

CIMZIA is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.*

IMPORTANT SAFETY INFORMATION:

Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member.

The information contained in this guide is for educational purposes only, and is intended to assist healthcare professionals in understanding the reimbursement process for CIMZIA when appropriately prescribed or administered. The information is not intended to provide specific guidance on how to code, bill, or charge for any product or service. It is the sole responsibility of the healthcare provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. Coding, coverage, and reimbursement may vary significantly by the payer, plan, patient, and setting of care. Healthcare providers should contact insurers to verify coverage and correct coding procedures prior to submitting claims, as information on coverage and coding is subject to change without notice. UCB, Inc., cannot guarantee payment of any claim.

*CIMZIA is also indicated for other uses. Please visit cimziaHCP.com for more information.

Please see Important Safety Information on page 6, refer to accompanying full Prescribing Information, and visit CIMZIAhcp.com.

CIMZIA® (certolizumab pegol) lyophilized powder for reconstitution (CIMZIA LYO) is supplied as a sterile, white, lyophilized powder in a single dose vial for subcutaneous use

CIMZIA Lyophilized Powder for Reconstitution

2 x 200 mg vials
NDC Number: 50474-700-62/50474-0700-62*

*For certain purposes, including the proper billing of drug products, an 11-digit NDC may be required.

The recommended dosage of CIMZIA for patients with pJIA is based on body weight

Total Body Weight	Initial Dosing	Vials used for Initial Dosing (week 0, 2 and 4)	Maintenance Dosing	Vials used for Maintenance Dosing (every other week)
10 kg (22 lbs) to less than 20 kg (44 lbs)	100 mg initially and at Weeks 2 and 4	1/2 of 200 mg vial	50 mg every other week	1/4 of 200 mg vial
20 kg (44 lbs) to less than 40 kg (88 lbs)	200 mg initially and at Weeks 2 and 4	1 x 200 mg vial	100 mg every other week	1/2 of 200 mg vial
Greater than or equal to 40 kg (88 lbs)	400 mg initially and at Weeks 2 and 4	2 x 200 mg vial	200 mg every other week	1 x 200 mg vial

Each vial is for one-time use only. **Discard any remaining solution.**

Note: If any drug amount is discarded or not administered to patient, a JW modifier may be required on claims billing for CIMZIA.

Please see Important Safety Information on page 6, refer to accompanying full Prescribing Information, and visit CIMZIAhcp.com.

cimzia® (certolizumab pegol)

Coding for CIMZIA in patients 2 years of age and older with pJIA

Diagnosis coding*†

The following list provides ICD-10-CM codes that may relate to the use of CIMZIA in pJIA patients

ICD-10-CM code	ICD-10-CM code description
M08.9#	Juvenile Arthritis, descriptors vary

*The number sign (#) is a placeholder. Please consult the ICD-10 code book for the digits related to each specific diagnosis within the general category listed.
†The Centers for Medicare and Medicaid Services (CMS) advises reporting specific diagnosis codes as supported by available medical record documentation and clinical knowledge of the patient's health condition at the time of that visit. In the absence of sufficient clinical information to support a specific code (for example, a diagnosis is not yet confirmed), it is acceptable to report the appropriate unspecified code. CMS advises against selecting a specific code that is not documented by the medical record or conducting unnecessary diagnostic testing in order to determine a more specific code.

Other relevant codes

The following codes may be relevant when filing claims for CIMZA in pJIA patients

Drug/biologic codes

Code Type	Code	Definition
HCPCS	J0717	Certolizumab pegol, 1 mg
HCPCS Modifier*	J0717-JW J0717-JZ	Drug amount discarded/not administered to any patient No drug was discarded
NDC codes *Lyophilized powder for reconstitution*	50474-0700-62	CIMZIA Kit: 2 × 200 mg lyophilized powder vials
NDC 5010 Electronic Transition Codes	N4 50474-0700-62 UN1	CIMZIA Kit: 2 x 200 mg lyophilized powder vials
NDC codes *Prefilled syringes†,‡*	50474-0710-81 50474-0710-79	CIMZIA Starter Kit: 6 × 200 mg/mL prefilled syringes CIMZIA Kit: 2 × 200 mg/mL prefilled syringes

Note for the JZ modifier for single-use containers: If no drug was discarded, the JZ modifier should be used. If any of the drug was not used, the JW modifier should be used.

Note: There is no dosage form for CIMZIA that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a healthcare professional using the vial kit.

*Not all plans require the HCPCS JW and JZ Modifiers. Check with your state Medicaid and commercial payers for their specific requirements.
†UnitedHealthcare® requires inclusion of the NDC for all medical claims on commercial and Medicare Advantage plans.
‡After proper training in subcutaneous injection technique, a patient may self-inject with the CIMZIA prefilled syringe if a physician determines that it is appropriate.

Drug administration codes

Code Type	Code	Definition
CPT	96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular
CPT	96401	Chemotherapy administration; subcutaneous or intramuscular

Please contact your payers individually for specific guidance regarding their approved administration codes for CIMZIA.

Revenue codes*

Code Type	Code	Definition
Revenue	0636	Drugs requiring detailed coding
Revenue	0330	Radiology - therapeutic
Revenue	0331	Radiology - therapeutic; chemotherapy - injected

*For hospital setting.

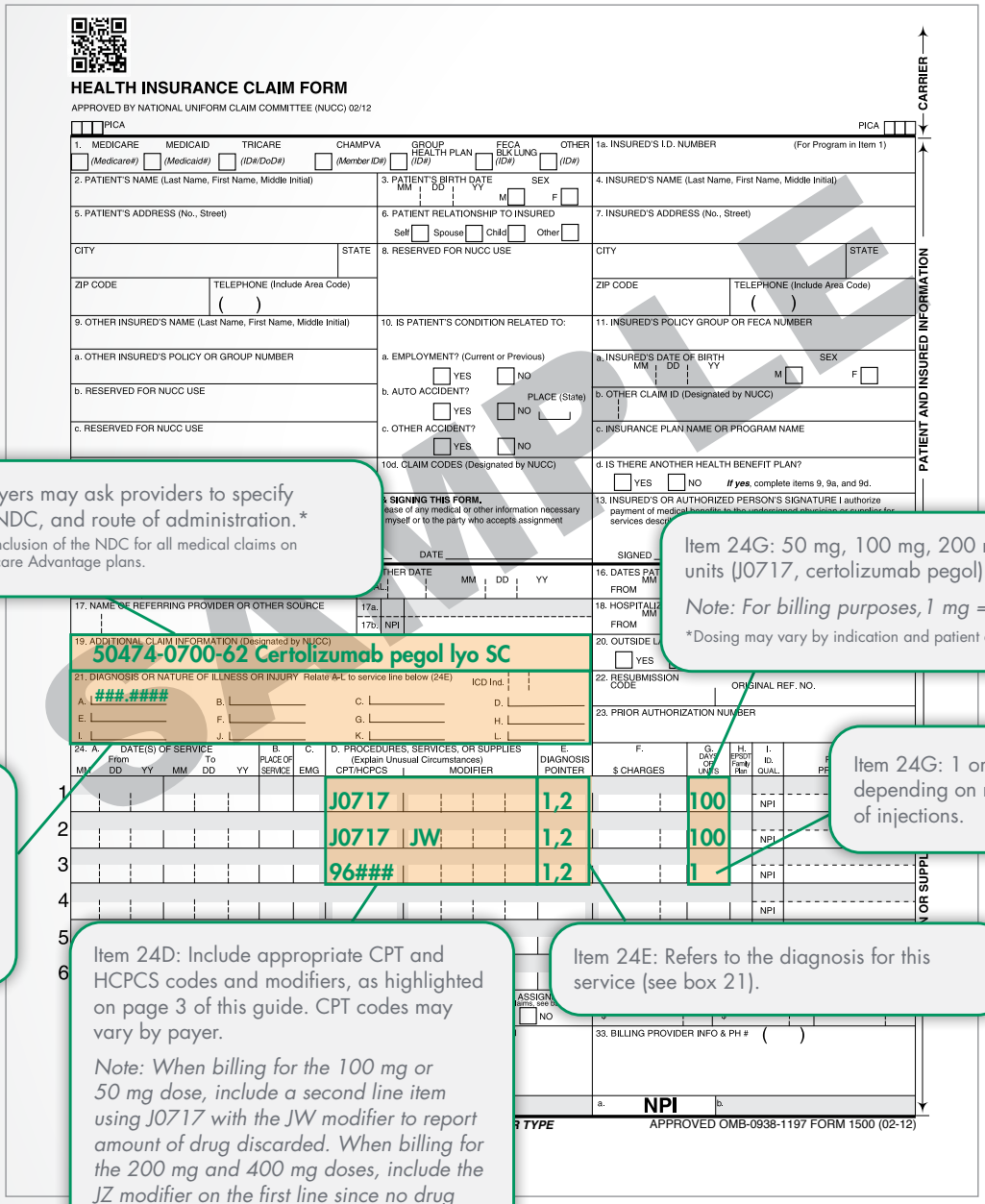
Please see Important Safety Information on page 6, refer to accompanying full Prescribing Information, and visit CIMZIAhcp.com.

cimzia® (certolizumab pegol)

Sample Claim Forms

Sample CMS-1500 and CMS-1450/UB-04 forms are provided below as general examples of the application of various codes. Remember, if claim forms are not accurately completed, there is a risk of denial or delay in payment for CIMZIA and its administration.

CIMZIA® (certolizumab pegol) CMS-1500 sample claim form: physician office



Item 19: Some payers may ask providers to specify CIMZIA dosage, NDC, and route of administration.*

*Some payers require inclusion of the NDC for all medical claims on commercial and Medicare Advantage plans.

Item 24G: 50 mg, 100 mg, 200 mg, or 400 mg units (J0717, certolizumab pegol).*

Note: For billing purposes, 1 mg = 1 unit of drug.

*Dosing may vary by indication and patient demographic.

Item 21: Include appropriate ICD-10 diagnosis code. Consult your ICD-10-CM coding manual for a complete list of specific codes.

Item 24G: 1 or 2 units, depending on number of injections.

Item 24D: Include appropriate CPT and HCPCS codes and modifiers, as highlighted on page 3 of this guide. CPT codes may vary by payer.

Note: When billing for the 100 mg or 50 mg dose, include a second line item using J0717 with the JW modifier to report amount of drug discarded. When billing for the 200 mg and 400 mg doses, include the JZ modifier on the first line since no drug is wasted.

Item 24E: Refers to the diagnosis for this service (see box 21).

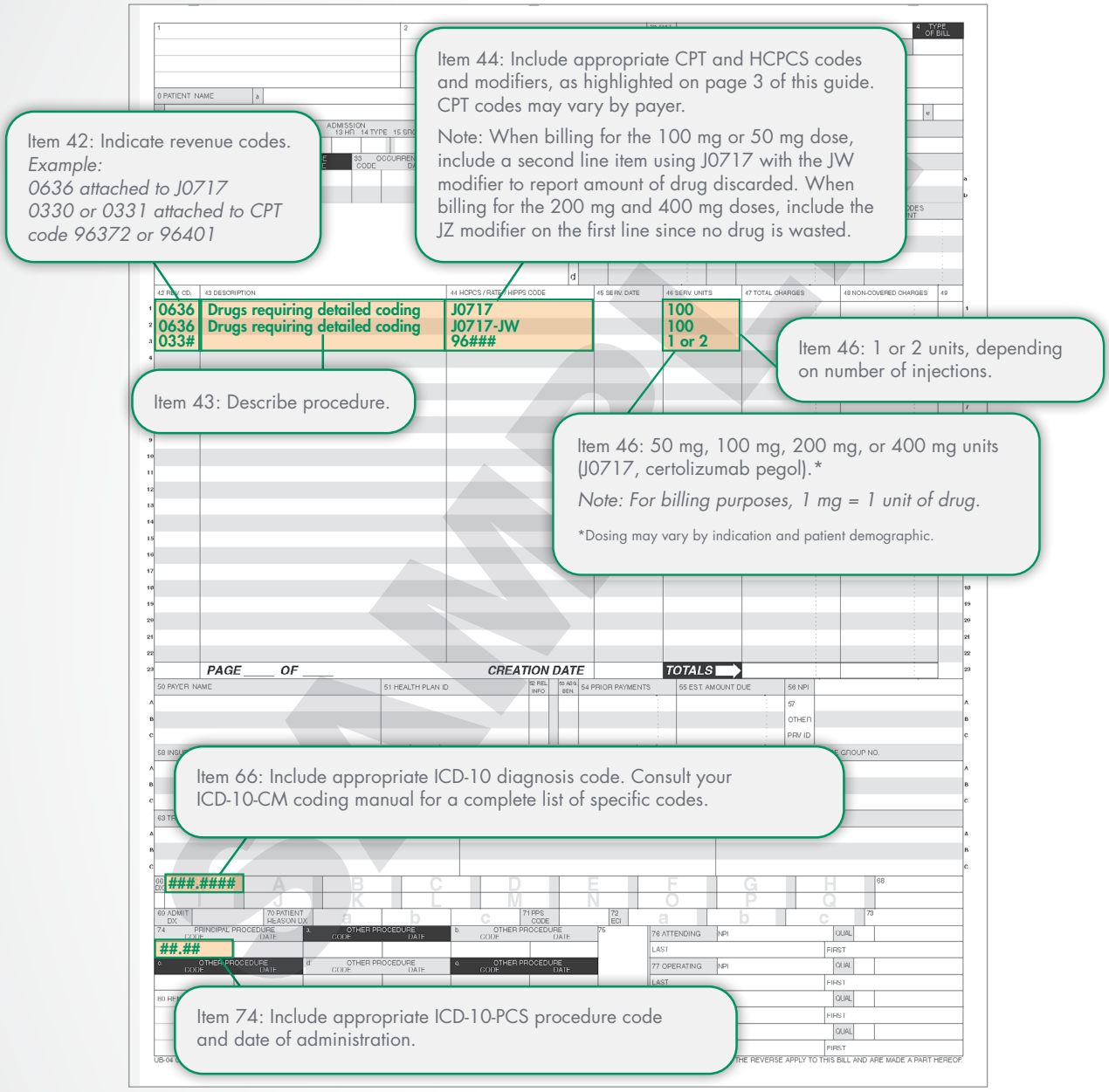
This CIMZIA CMS-1500 sample claim form is intended solely as a resource tool to assist billing staff regarding reimbursement issues. Any determination about if and how to seek reimbursement should be made only by the appropriate members of the physician's office in consultation with the physician and in consideration of the procedure performed or therapy provided to a specific patient. Payers may require physicians to report different codes when billing for CIMZIA. We recommend verifying a health plan's coding policies. For more information on specific policies and other questions, contact the health plan.

Note: The coding information contained herein is gathered from various resources and is subject to change. Healthcare providers should select the most appropriate codes with the highest level of detail to describe the patient's condition and the services rendered to the patient. It is the healthcare provider's sole responsibility to determine and submit appropriate codes. Healthcare providers should contact insurers to verify coverage and correct coding procedures prior to submitting claims, as information on coverage and coding is subject to change without notice.

cimzia® (certolizumab pegol)

Sample Claim Forms (continued)

CIMZIA® (certolizumab pegol) CMS-1450/UB-04 sample claim form: hospital



This CIMZIA CMS-1450/UB-04 sample claim form is intended solely as a resource tool to assist billing staff regarding reimbursement issues. Any determination about if and how to seek reimbursement should be made only by the appropriate members of the hospital staff in consultation with the physician and in consideration of the procedure performed or therapy provided to a specific patient. Payers may require physicians to report different codes when billing for CIMZIA. We recommend verifying a health plan's coding policies. For more information on specific policies and other questions, contact the health plan.

Note: The coding information contained herein is gathered from various resources and is subject to change. Healthcare providers should select the most appropriate codes with the highest level of detail to describe the patient's condition and the services rendered to the patient. It is the healthcare provider's sole responsibility to determine and submit appropriate codes. Healthcare providers should contact insurers to verify coverage and correct coding procedures prior to submitting claims, as information on coverage and coding is subject to change without notice.

Please see Important Safety Information on page 6, refer to accompanying full Prescribing Information, and visit CIMZIAhcp.com.

cimzia® (certolizumab pegol)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.

- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex that may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDS.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Avoid use of live vaccines during or immediately prior to initiating CIMZIA. Update immunizations in agreement with current immunization guidelines prior to initiating CIMZIA therapy.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

Please see full Prescribing Information provided by the UCB representative and visit www.CIMZIAhcp.com.

cimzia® (certolizumab pegol)