ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

OnCall™
ORENCIA® (abatacept) Support Program

A Reference Guide to Reimbursement and Coding ORENCIA® (abatacept)

Please click here to see Important Safety Information on pages 35-36 and click here for Full Prescribing Information.

Indications and Usage

Adult Rheumatoid Arthritis: ORENCIA® (abatacept) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

Polyarticular Juvenile Idiopathic Arthritis: ORENCIA® (abatacept) is indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA).

Psoriatic Arthritis: ORENCIA® (abatacept) is indicated for the treatment of patients 2 years of age and older with active psoriatic arthritis (PsA).

Prophylaxis for Acute Graft versus Host Disease: ORENCIA® (abatacept) is indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor (CNI) and methotrexate (MTX), in adults and pediatric patients 2 years of age or older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

Limitations of Use: The concomitant use of ORENCIA® with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

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For reimbursement assistance, call ORENCIA On Call™ Support Program at 1-800-ORENCIA (673-6242) 8 AM to 8 PM ET, Monday–Friday, or visit www.ORENCIAhcp.com.

Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to ORENCIA by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that rheumatology offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and best coding practices.

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Healthcare Common Procedure Coding System (HCPCS) and Revenue Codes for ORENCIA® (abatacept)

Recommended HCPCS Code for ORENCIA[1]		
HCPCS Code	**Description**	**Billing Units**
J0129	Injection, abatacept, 10 mg	10 mg = 1 billing unit

Use the following claim formats when ORENCIA is administered to patients on an outpatient basis and billed to health plans:

- Physician office: CMS-1500 (paper format) or ASC 837P (electronic format)[2]
- Hospital outpatient: UB-04 (CMS-1450) (paper format) or ASC 837I (electronic format)[2]

Select payers may require route of administration modifiers:

- JA modifier: administered intravenously
- JB modifier: administered subcutaneously
- JZ modifier: Effective 7/1/2023, JZ modifier will be required, on the same service line as the drug CPT code, when there are no discarded amounts from single use vials or single use packages payable under Part B for which the JW modifier would be required if there were discarded amounts

(Please contact payer for additional coding information.)

Home Infusion/Ambulatory Infusion Suite Only

- Ambulatory Infusion Suite: CMS-1500 (paper format) or ASC 837P (electronic format)[3]
- Home Infusion: CMS-1500 (paper format) or ASC 837P (electronic format)[3]*
- S9379 Not Otherwise Classified – Infusion for site of service home[3]*
- S9542 Injectable Therapies including subcutaneous[3]*

-OR-

- S9338 Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem[3]
- SS modifier: Home infusion services provided in the infusion suite of the IV therapy provider[3]

ORENCIA On Call™ does not guarantee or provide any explicit or implicit warranty of coding, coverage, or reimbursement. Coding, coverage, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims.

All the coding information presented is applicable to outpatient procedures only. Please see pages 24-26 for more information.

*Additional claim notes may be required.

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Healthcare Common Procedure Coding System (HCPCS) and Revenue Codes for ORENCIA® (abatacept) (cont'd)

Revenue Codes[4] (for Use in the Hospital Outpatient Setting)	
Revenue Code	**Description**
0260	IV solutions
0335	Chemotherapy administration, IV
0636	Drugs requiring detailed coding

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CPT Codes for ORENCIA® (abatacept)

CPT Codes

The Current Procedural Terminology (CPT)* codes that may be appropriate when administering ORENCIA appear in the table below[5]:

The National Drug Codes (NDCs) for ORENCIA, listed in the table below, are often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

Recommended CPT Codes for ORENCIA	
CPT Code	**Description**
CPT Codes for Intravenous Use Only[5]	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug (applicable to Medicare and non-Medicare patients)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour (applicable to Medicare and non-Medicare patients)
CPT Code for Subcutaneous Injection Only[5]	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular (applicable to Medicare and non-Medicare patients)

Recommended CPT Code for Home Infusion[5]	
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)

Please contact the payer or ORENCIA On Call™ for additional coding information regarding ORENCIA.

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National Drug Code (NDC) Information for ORENCIA® (abatacept)

The NDCs for ORENCIA, listed in the table below, are often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

NDC Code for Intravenous (IV) Use[6]	
00003-2187-10	11-digit NDC number (250 mg in a 15-mL single-use vial, in a clamshell presentation)
00003-2187-13	11-digit NDC number (250 mg in a 15-mL single-use vial, in a carton with a perforated push-through opening)

NDC Codes for Subcutaneous Injection[6]	
00003-2814-11	11-digit NDC number (pack of 4 syringes with a passive needle safety guard [50 mg/0.4 mL pre-filled syringe])
00003-2818-11	11-digit NDC number (pack of 4 syringes with a passive needle safety guard [87.5 mg/0.7 mL pre-filled syringe])
00003-2188-11	11-digit NDC number (pack of 4 syringes with a passive needle safety guard [125 mg/1 mL pre-filled syringe])
NDC Code for ClickJect™ Autoinjector[6]	
00003-2188-51	11-digit NDC number (pack of 4 autoinjectors [125 mg/1 mL])

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5010 Electronic Transaction Codes for ORENCIA® (abatacept)

- For electronic transactions, including 837P and 837I, the NDC is to be preceded by the qualifier N4 and followed immediately by the 11-digit NDC code for payers that require it[7]
- This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter), and the quantity administered[7]

5010 Transaction Codes for ORENCIA[6]

How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
250 mg in a 15-mL single-use vial	00003-2187-13	N4	UN	N400003218710UN1*
Pack of 4 syringes with a passive needle safety guard (125 mg/1 mL prefilled syringe)	00003-2188-11	N4	ML	N400003218811ML4*
Pack of 4 autoinjectors (125 mg/1 mL)	00003-2188-51	N4	ML	N400003218851ML4*

*The examples given in the far right column demonstrate NDC quantity reporting for 1 vial, 4 prefilled syringes, or 4 autoinjectors of ORENCIA. The actual amount of drug used can vary based on factors such as indication or patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept)

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States.

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters
- The ICD-10-CM codes for the labeled indication for ORENCIA are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call ORENCIA On Call™ at **1-800-ORENCIA (673-6242)** or visit **www.ORENCIAhcp.com**.

ICD-10-CM Codes for ORENCIA[8]	
M05.7 Rheumatoid arthritis with rheumatoid factor without organ or systems involvement	
M05.70	**Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement**
M05.71	**Rheumatoid arthritis with rheumatoid factor of shoulder without organ or systems involvement***
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement

(more M05.7 codes on the next page)

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M05.72	**Rheumatoid arthritis with rheumatoid factor of elbow without organ or systems involvement***
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement
M05.73	**Rheumatoid arthritis with rheumatoid factor of wrist without organ or systems involvement***
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.74	**Rheumatoid arthritis with rheumatoid factor of hand without organ or systems involvement***
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement

(more M05.7 codes on the next page)

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M05.75	**Rheumatoid arthritis with rheumatoid factor of hip without organ or systems involvement***
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.76	**Rheumatoid arthritis with rheumatoid factor of knee without organ or systems involvement***
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.77	**Rheumatoid arthritis with rheumatoid factor of ankle and foot without organ or systems involvement***
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement
M05.79	**Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement**
M05.7A	**Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement**

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M05.8	**Other rheumatoid arthritis with rheumatoid factor**
M05.80	**Other rheumatoid arthritis with rheumatoid factor of unspecified site**
M05.81	**Other rheumatoid arthritis with rheumatoid factor of shoulder***
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.82	**Other rheumatoid arthritis with rheumatoid factor of elbow***
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.83	**Other rheumatoid arthritis with rheumatoid factor of wrist***
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist

(more M05.8 codes on the next page)

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M05.84	**Other rheumatoid arthritis with rheumatoid factor of hand***
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.85	**Other rheumatoid arthritis with rheumatoid factor of hip***
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.86	**Other rheumatoid arthritis with rheumatoid factor of knee***
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.87	**Other rheumatoid arthritis with rheumatoid factor of ankle and foot***
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	**Other rheumatoid arthritis with rheumatoid factor of multiple sites**
M05.8A	**Other rheumatoid arthritis with rheumatoid factor of other specified site**
M05.9	**Rheumatoid arthritis with rheumatoid factor, unspecified**

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M06.0	**Rheumatoid arthritis without rheumatoid factor**
M06.00	**Rheumatoid arthritis without rheumatoid factor, unspecified site**
M06.01	**Rheumatoid arthritis without rheumatoid factor, shoulder***
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.02	**Rheumatoid arthritis without rheumatoid factor, elbow***
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.03	**Rheumatoid arthritis without rheumatoid factor, wrist***
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.04	**Rheumatoid arthritis without rheumatoid factor, hand***
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand

(more M06.0 codes on the next page)

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Adult Rheumatoid Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M06.05	**Rheumatoid arthritis without rheumatoid factor, hip***
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.06	**Rheumatoid arthritis without rheumatoid factor, knee***
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.07	**Rheumatoid arthritis without rheumatoid factor, ankle and foot***
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	**Rheumatoid arthritis without rheumatoid factor, vertebrae**
M06.09	**Rheumatoid arthritis without rheumatoid factor, multiple sites**
M06.0A	**Rheumatoid arthritis without rheumatoid factor, other specified site**
M06.8A	**Other specified rheumatoid arthritis, other specified site**

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Juvenile Idiopathic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept)

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- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters
- The ICD-10-CM codes for the labeled indication for ORENCIA are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call ORENCIA On Call™ at **1-800-ORENCIA (673-6242)** or visit **www.ORENCIAhcp.com**.

For patients with moderate to severe juvenile idiopathic arthritis (JIA), ORENCIA may be administered as an intravenous infusion (6 years of age and older) or a subcutaneous injection (2 years of age and older). Intravenous dosing has not been studied in patients younger than 6 years of age. The safety and efficacy of ORENCIA ClickJect™ autoinjector for subcutaneous injection have not been studied in patients under 18 years of age.

ICD-10-CM Codes for ORENCIA[8]	
M08.0 Unspecified juvenile rheumatoid arthritis	
M08.00	**Unspecified juvenile rheumatoid arthritis of unspecified site**
M08.01	**Unspecified juvenile rheumatoid arthritis, shoulder***
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.02	**Unspecified juvenile rheumatoid arthritis, elbow***
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow

(more M08.0 codes on the next page)

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ICD-10-CM Codes for ORENCIA[8]	
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.03	**Unspecified juvenile rheumatoid arthritis, wrist***
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.04	**Unspecified juvenile rheumatoid arthritis, hand***
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.05	**Unspecified juvenile rheumatoid arthritis, hip***
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.06	**Unspecified juvenile rheumatoid arthritis, knee***
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee

(more M08.0 codes on the next page)

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Juvenile Idiopathic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M08.07	**Unspecified juvenile rheumatoid arthritis, ankle and foot***
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	**Unspecified juvenile rheumatoid arthritis, vertebrae**
M08.09	**Unspecified juvenile rheumatoid arthritis, multiple sites**
M08.0A	**Unspecified juvenile rheumatoid arthritis, other specified site**
M08.2	**Juvenile rheumatoid arthritis with systemic onset**
M08.20	**Juvenile rheumatoid arthritis with systemic onset, unspecified site**
M08.21	**Juvenile rheumatoid arthritis with systemic onset, shoulder***
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.22	**Juvenile rheumatoid arthritis with systemic onset, elbow***
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow

(more M08.2 codes on the next page)

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For reimbursement assistance, call ORENCIA On Call™ Support Program at 1-800-ORENCIA (673-6242) 8 AM to 8 PM ET, Monday–Friday, or visit www.ORENCIAhcp.com.

Juvenile Idiopathic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M08.23	**Juvenile rheumatoid arthritis with systemic onset, wrist***
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.24	**Juvenile rheumatoid arthritis with systemic onset, hand***
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.25	**Juvenile rheumatoid arthritis with systemic onset, hip***
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.26	**Juvenile rheumatoid arthritis with systemic onset, knee***
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee

(more M08.2 codes on the next page)

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

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Juvenile Idiopathic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M08.27	**Juvenile rheumatoid arthritis with systemic onset, ankle and foot***
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	**Juvenile rheumatoid arthritis with systemic onset, vertebrae**
M08.29	**Juvenile rheumatoid arthritis with systemic onset, multiple sites**
M08.2A	**Juvenile rheumatoid arthritis with systemic onset, other specified site**
M08.3	**Juvenile rheumatoid polyarthritis (seronegative)**
M08.4	**Pauciarticular juvenile rheumatoid arthritis**
M08.40	**Pauciarticular juvenile rheumatoid arthritis, unspecified site**
M08.41	**Pauciarticular juvenile rheumatoid arthritis, shoulder***
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder
M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder
M08.42	**Pauciarticular juvenile rheumatoid arthritis, elbow***
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow

(more M08.4 codes on the next page)

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Juvenile Idiopathic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M08.43	**Pauciarticular juvenile rheumatoid arthritis, wrist***
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist
M08.44	**Pauciarticular juvenile rheumatoid arthritis, hand***
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand
M08.45	**Pauciarticular juvenile rheumatoid arthritis, hip***
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip
M08.46	**Pauciarticular juvenile rheumatoid arthritis, knee***
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee

(more M08.4 codes on the next page)

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Juvenile Idiopathic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept) (cont'd)

ICD-10-CM Codes for ORENCIA[8]	
M08.47	**Pauciarticular juvenile rheumatoid arthritis, ankle and foot***
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot
M08.48	**Pauciarticular juvenile rheumatoid arthritis, vertebrae**
M08.4A	**Pauciarticular juvenile rheumatoid arthritis, other specified site**

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Adult Psoriatic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept)

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States.

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters
- The ICD-10-CM codes for the labeled indication for ORENCIA are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call ORENCIA On Call™ at **1-800-ORENCIA (673-6242)** or visit **www.ORENCIAhcp.com**.

ICD-10-CM Codes for ORENCIA[8]

L40 Psoriasis	
L40.5	**Arthropathic psoriasis***
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

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Juvenile Psoriatic Arthritis: ICD-10-CM Codes for ORENCIA® (abatacept)

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States.

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- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters
- The ICD-10-CM codes for the labeled indication for ORENCIA are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call ORENCIA On Call™ at **1-800-ORENCIA (673-6242)** or visit **www.ORENCIAhcp.com**.

ICD-10-CM Codes for ORENCIA[8]

L40 Psoriasis	
L40.5	**Arthropathic psoriasis***
L40.54	Psoriatic Juvenile Arthropathy

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

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Prophylaxis for Acute Graft vs. Host Disease (aGVHD): ICD-10-CM Codes for ORENCIA® (abatacept)

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States.

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters
- The ICD-10-CM codes for the labeled indication for ORENCIA are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call ORENCIA On Call™ at **1-800-ORENCIA (673-6242)** or visit **www.ORENCIAhcp.com**.

ORENCIA is indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor (CNI) and methotrexate (MTX), in adults and pediatric patients 2 years of age or older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

ICD-10-CM Codes for ORENCIA[8]	
D89.81	Graft-versus-host disease
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft versus host disease: (acute exacerbation of a chronic GVHD status, or acute manifestation of a preexisting GVHD associated condition)
D89.813	Graft-versus-host disease, unspecified

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Coding and Billing Units for ORENCIA® (abatacept)

Please contact the payer or ORENCIA On Call™ for additional information on coding and billing units.

CMS-1500 Form

This sample form is for informational purposes only.

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Physician Office

A **Item 19:** Many payers require detailed information about the drug in Box 19.[7] Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

B **Item 21:** Indicate diagnosis using appropriate ICD-10-CM code[7]

C **Item 24B:** A Place of Service code of 11-Office should be used when billing for infusion services in a physician office

D **Item 24D:** When administering ORENCIA IV, enter J0129. Enter CPT code 96413 or 96365; however, payer policies may vary in regard to which administration codes are appropriate[1,5,7]

Modifiers: some payers may require a modifier. Please check with your payer.

E **Item 24G:** When ORENCIA IV is administered, each billing unit represents abatacept 10 mg; for example, write "50" units for 500 mg, "75" units for 750 mg, or "100" units for 1,000 mg. See Dosing and Administration

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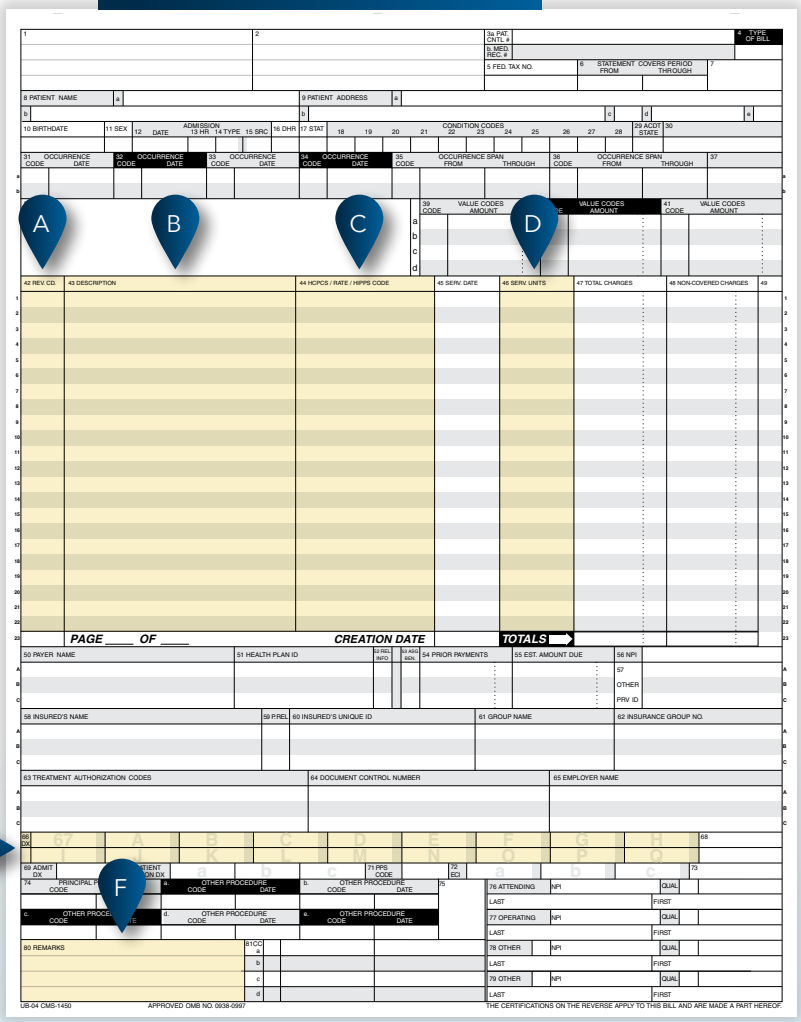
Coding and Billing Units for ORENCIA® (abatacept) (cont'd)

UB-04 Form



Outpatient Hospital

A **Form Locator (FL) 42:** Enter a 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.[9] Revenue codes 0636 (drugs requiring detailed coding), 0250 (general pharmacy), or 0260 (IV therapy) could be used[4]

B **FL 43:** Describe procedure (eg, therapeutic injection, clinic visit)[9]

C **FL 44:** Enter HCPCS J0129. Enter CPT code 96413 or 96365; however, payer policies may vary in regard to which administration codes are appropriate[1,5,9]

Modifiers: some payers may require a modifier. Please check with your payer.

D **FL 46:** When ORENCIA IV is administered, each billing unit represents abatacept 10 mg; for example, write "50" units for 500 mg, "75" units for 750 mg, or "100" units for 1,000 mg. See Dosing and Administration

E **FL 66:** Indicate diagnosis using appropriate ICD-10-CM code[9]

F **FL 80:** Many payers require detailed information about the drug in FL 80.[7,9] Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

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Coding and Billing Units for ORENCIA® (abatacept) (cont'd)

Please contact the payer or ORENCIA On Call™ for additional information on coding and billing units.

CMS-1500 Form

This sample form is for informational purposes only.

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Home Infusion/Ambulatory Infusion Suite

A **Item 19:** Many payers require detailed information about the drug in Box 19.[7] Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

B **Item 21:** Indicate diagnosis using appropriate ICD-10-CM code[7]

C **Item 24B:** A Place of Service code of 12-Home or 49-Independent Clinic should be used when billing for home infusion or ambulatory infusion suite (AIS) services

D **Item 24D:** When administering ORENCIA IV, enter J0129. When administering in the home setting, CPT code 99601 [Home Infusion] may be used for a visit up to 2 hours. Enter CPT codes S9379*, S9542*, or S9338. If the infusion is performed in an ambulatory infusion suite (AIS), modifier -SS should be added to the Per Diem code, J-code and Nursing code. Payer policies may vary in regard to which codes are appropriate[1,5,7]

E **Item 24G:** When ORENCIA IV is administered, each billing unit represents abatacept 10 mg; for example, write "50" units for 500 mg, "75" units for 750 mg, or "100" units for 1,000 mg. See Dosing and Administration

Guidelines for billing home infusion or ambulatory infusion suite may vary; please check with the payer for their specific guidelines

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Dosing and Administration for ORENCIA® (abatacept)

Adult Moderate to Severe Rheumatoid Arthritis[6]

- For these patients, ORENCIA may be administered as an intravenous infusion or a subcutaneous injection
- ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists

Intravenous Dosing Regimen[6]

- ORENCIA lyophilized powder should be reconstituted and administered after dilution as a 30-minute intravenous infusion utilizing the weight range–based dosing specified in the table below
- Following the initial intravenous administration, an intravenous infusion should be given at 2 and 4 weeks after the first infusion and every 4 weeks thereafter

Dose of ORENCIA for Intravenous Infusion[6]

Body Weight of Patient	Dose	# of Vials*
Less than 60 kg	500 mg	2
60-100 kg	750 mg	3
More than 100 kg	1000 mg	4

*Each vial provides 250 mg of abatacept for administration.

Subcutaneous Dosing Regimen[6]

- ORENCIA 125 mg in prefilled syringes or in ORENCIA ClickJect™ autoinjector should be administered by subcutaneous injection once weekly and may be initiated with or without an intravenous loading dose
  - For patients initiating therapy with an intravenous loading dose, ORENCIA should be initiated with a single intravenous infusion (as per body weight categories listed in the table above), followed by the first 125 mg subcutaneous injection administered within a day of the intravenous infusion
- Patients transitioning from ORENCIA intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose

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Dosing and Administration for ORENCIA® (abatacept) (cont'd)

Juvenile Idiopathic Arthritis[6]

- For patients with JIA, ORENCIA may be administered as an intravenous infusion (6 years of age and older) or a subcutaneous injection (2 years of age and older). Intravenous dosing has not been studied in patients younger than 6 years of age
- ORENCIA may be used as monotherapy or concomitantly with methotrexate

Intravenous Dosing Regimen[6]

- ORENCIA should be administered as a 30-minute intravenous infusion based on body weight. Pediatric patients with:
  - Body weight less than 75 kg should be administered ORENCIA at a dose of 10 mg/kg
  - Body weight of 75 kg or more should be administered ORENCIA following the adult intravenous dosing regimen (see dosing table on previous page), not to exceed a maximum dose of 1000 mg
- Following the initial administration, ORENCIA should be given at 2 and 4 weeks after the first infusion and every 4 weeks thereafter
- Any unused portions in the vials must be immediately discarded

Subcutaneous Dosing Regimen[6]

- ORENCIA for subcutaneous injection should be initiated without an intravenous loading dose and be administered utilizing the weight range–based dosing in the table below
- The safety and efficacy of ORENCIA ClickJect™ autoinjector for subcutaneous injection have not been studied in patients under 18 years of age

Subcutaneous Administration for Juvenile Idiopathic Arthritis

Body Weight of Patient	Dose (once weekly)
10 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

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Dosing and Administration for ORENCIA® (abatacept) (cont'd)

Adult Psoriatic Arthritis[6]

- For these patients, ORENCIA may be administered as an intravenous infusion or a subcutaneous injection
- ORENCIA can be used with or without nonbiologic DMARDs

Intravenous Dosing Regimen[6]

- ORENCIA IV should be administered as a 30-minute intravenous infusion utilizing the weight range–based dosing specified in the "Dose of ORENCIA for Intravenous Infusion" table on page 27
- Following the initial intravenous administration, an intravenous infusion should be given at 2 and 4 weeks after the first infusion and every 4 weeks thereafter

Subcutaneous Dosing Regimen[6]

- ORENCIA SC 125 mg should be administered by subcutaneous injection once weekly without the need for an intravenous loading dose
- Patients switching from ORENCIA intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose

Psoriatic Arthritis in Pediatric Patients ≥2 Years Old[6]

Administer subcutaneously without an intravenous loading dose	
Body Weight of Pediatric Patient	**Dose (once weekly)**
10 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

Intravenous administration is not approved for pediatric patients with psoriatic arthritis

Please click here to see Important Safety Information on pages 35-36 and click here for Full Prescribing Information.

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Dosing and Administration for ORENCIA® (abatacept) (cont'd)

Prophylaxis of Acute Graft vs. Host Disease (aGVHD)[6]

- Prophylaxis of aGVHD in adults and pediatric patients aged 2 years and older

Antiviral Prophylaxis Treatment

- Before administering ORENCIA, administer recommended antiviral prophylactic treatment for Epstein-Barr virus (EBV) reactivation, and continue for 6 months following HSCT. In addition, consider prophylactic antivirals for CMV infection/reactivation during treatment and for 6 months following HSCT

Intravenous Dosing Regimen

- For patients 6 years and older, administer ORENCIA 10mg/kg (maximum dose of 1000 mg) as an intravenous infusion over 60 minutes on the day before transplantation (Day -1), followed by administration on Days 5, 14, and 28 after transplantation
- For patients 2 to less than 6 years old, administer ORENCIA 15 mg/kg as an intravenous infusion over 60 minutes on the day before transplantation (Day -1), followed by 12 mg/kg as an intravenous infusion over 60 minutes on Days 5, 14, and 28 after transplantation

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Drug Reimbursement for ORENCIA® (abatacept) IV

What is the Medicare reimbursement allowable for ORENCIA IV?

Physicians*

- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents one billing unit of ORENCIA, which is billed for each 10 mg of ORENCIA IV (10 mg = 1 billing unit)[10†]
- The amount paid to physicians for ORENCIA HCPCS code J0129 is published each quarter in "Payment Allowance Limits for Medicare Part B Drugs,"[11] which can be downloaded at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files
- Medicare Part B will pay physicians 80% of the allowed price for J0129; the patient is responsible for 20% coinsurance after the deductible is met, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc)[12]

Hospital outpatient facilities*

- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents one billing unit as established by the Centers for Medicare & Medicaid Services (CMS). The billing unit is usually consistent with the unit of measure for that drug (grams, milligrams, units, etc). This is 10 mg of ORENCIA IV for J0129 (10 mg = 1 billing unit)[10†]
- The Payment Allowance Limits[11] are published each quarter at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs.[13,14] This prospective rate does not allow for drugs to be paid separately[15]

*While the statutory amount that Medicare will reimburse for a Part B drug in a physician office will remain at ASP+6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[16]

†See the Centers for Medicare & Medicaid Services' (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

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Drug Reimbursement for ORENCIA® (abatacept) IV (cont'd)

How is the reimbursement amount for ORENCIA IV determined by commercial insurers?

- Most commercial insurers pay for drug services under an ASP plus markup reimbursement model for each item or service billed[17]
- Pricing for drugs may be based on the insurer's fee schedule, publicly available drug pricing (eg, Average Sales Price, Average Wholesale Price), average charges for the area ("Usual, Reasonable & Customary"), or a percentage of what the provider charges[17-20]
- An exception to the above pricing is when a provider utilizes a capitated monthly rate for members, from which specific services are excluded (handled separately). These are referred to as "carve-outs"[21]
  - Drugs (pharmacy benefit) may be carved out of the primary health coverage plan
- If the amount received by the provider for HCPCS code J0129 from a commercial insurer is not the expected amount, the provider can contact the commercial insurer to request a correction[22]

Please click here to see Important Safety Information on pages 35-36 and click here for Full Prescribing Information.

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Important Safety Information for ORENCIA® (abatacept)

Increased Risk of Infection with Concomitant Use with TNF Antagonists, Other Biologic RA/PsA Therapy, or JAK Inhibitors: Concurrent therapy with ORENCIA and a TNF antagonist is not recommended. In controlled clinical trials, adult moderate to severe rheumatoid arthritis (RA) patients receiving concomitant intravenous ORENCIA and TNF antagonist therapy experienced more infections (63% vs 43%) and serious infections (4.4% vs 0.8%) compared to patients treated with only TNF antagonists, without an important enhancement of efficacy. Additionally, concomitant use of ORENCIA with other biologic RA/PsA therapy or JAK inhibitors is not recommended.

Hypersensitivity Reactions: There were 2 cases (<0.1%; n=2688) of anaphylaxis reactions in clinical trials with adult RA patients treated with intravenous ORENCIA. Other reactions potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in <0.9% of patients. There was one case of a hypersensitivity reaction with ORENCIA in pJIA clinical trials (0.5%; n=190). In postmarketing experience, fatal anaphylaxis following the first infusion of ORENCIA and life-threatening cases of angioedema have been reported. Angioedema has occurred as early as after the first dose of ORENCIA, but also has occurred with subsequent doses. Angioedema reactions have occurred within hours of administration and in some instances had a delayed onset (i.e., days). Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use. If an anaphylactic or other serious allergic reaction occurs, administration of intravenous or subcutaneous ORENCIA should be stopped immediately and permanently discontinued, with appropriate therapy instituted.

Infections: Serious infections, including sepsis and pneumonia, were reported in 3% and 1.9% of RA patients treated with intravenous ORENCIA and placebo, respectively. Some of these infections have been fatal. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy which, in addition to their underlying disease, could further predispose them to infection. Caution should be exercised in patients with a history of infection or underlying conditions which may predispose them to infections. Treatment with ORENCIA should be discontinued if a patient develops a serious infection. Patients should be screened for tuberculosis and viral hepatitis in accordance with published guidelines, and if positive, treated according to standard medical practice prior to therapy with ORENCIA.

Immunizations: Prior to initiating ORENCIA in pediatric and adult patients, update vaccinations in accordance with current vaccination guidelines. ORENCIA-treated patients may receive current non-live vaccines. Live vaccines should not be given concurrently with ORENCIA or within 3 months after discontinuation. ORENCIA may blunt the effectiveness of some immunizations. In addition, it is unknown if the immune response of an infant who was exposed in utero to abatacept and subsequently administered a live vaccine is impacted. Risks and benefits should be considered prior to vaccinating such infants.

Increased Risk of Adverse Reactions When Used in Patients with Chronic Obstructive Pulmonary Disease (COPD): In Study V, adult COPD patients treated with ORENCIA for RA developed adverse reactions more frequently than those treated with placebo, including COPD exacerbations, cough, rhonchi, and dyspnea. In the study, 97% of COPD patients treated with ORENCIA developed adverse events versus 88% treated with placebo. Respiratory disorders occurred more frequently in patients treated with ORENCIA compared to those on placebo (43% vs 24%, respectively), including COPD exacerbation, cough, rhonchi, and dyspnea. A greater percentage of patients treated with ORENCIA developed a serious adverse event compared to those on placebo (27% vs 6%), including COPD exacerbation [3 of 37 patients (8%)] and pneumonia [1 of 37 patients (3%)]. Use of ORENCIA in patients with COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status.

Immunosuppression: In clinical trials in adult RA patients, a higher rate of infections was seen in ORENCIA-treated patients compared to placebo-treated patients. The impact of treatment with ORENCIA on the development and course of malignancies is not fully understood. There have been reports of malignancies, including skin cancer in patients receiving ORENCIA. Periodic skin examinations are recommended for all ORENCIA-treated patients, particularly those with risk factors for skin cancer.

Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) Reactivation in aGVHD Prophylaxis after Hematopoietic Stem Cell Transplant (HSCT): Post-Transplant Lymphoproliferative Disorder (PTLD) occurred in patients who received ORENCIA for aGVHD prophylaxis during unrelated HSCT. Of 116 patients who received ORENCIA, 4 patients (3.4%) experienced PTLD. All the PTLD events were associated with Epstein-Barr virus (EBV) infection. The range of time to onset of the event was 49 to 89 days post-transplant. Monitor patients for EBV reactivation in accordance with institutional practices. Before administering ORENCIA, provide recommended prophylaxis for EBV infection and continue for 6 months post-transplantation to prevent EBV-associated PTLD. Cytomegalovirus (CMV) invasive disease occurred in patients who received ORENCIA for aGVHD prophylaxis during unrelated HSCT. Of 116 patients who received ORENCIA, 7% (n=8) experienced CMV invasive diseases up to day 225 post-transplant. The median time to onset of the event was 91 days post-transplant. CMV invasive diseases predominantly involved the gastrointestinal tract. Monitor patients for CMV infection/reactivation for 6 months post-transplant regardless of the results of donor and recipient pre-transplant CMV serology. Consider prophylaxis for CMV infection/reactivation during treatment and for six months following HSCT.

(continued on next page)

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Important Safety Information for ORENCIA® (abatacept) (cont'd)

Blood Glucose Testing: ORENCIA for intravenous administration contains maltose, which may result in falsely elevated blood glucose readings on the day of infusion when using blood glucose monitors with test strips utilizing glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ). Consider using monitors and advising patients to use monitors that do not react with maltose, such as those based on glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose oxidase or glucose hexokinase test methods. ORENCIA for subcutaneous (SC) administration does not contain maltose; therefore, patients do not need to alter their glucose monitoring.

Pregnancy: There are no adequate and well-controlled studies of ORENCIA use in pregnant women and the data with ORENCIA use in pregnant women are insufficient to inform on drug-associated risk. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to ORENCIA during pregnancy. Healthcare professionals are encouraged to register patients by calling 1-877-311-8972.

Lactation: There is no information regarding the presence of abatacept in human milk, the effects on the breastfed infant, or the effects on milk production. However, abatacept was present in the milk of lactating rats dosed with abatacept.

Most Serious Adverse Reactions: In controlled clinical trials, adult RA patients experienced serious infections (3% ORENCIA vs 1.9% placebo) and malignancies (1.3% ORENCIA vs 1.1% placebo). In the GVHD-1 study, serious adverse reactions reported in >5% of patients who received ORENCIA in combination with a calcineurin inhibitor and methotrexate included pyrexia (20%), pneumonia (8%), acute kidney injury (7%), diarrhea (6%), hypoxia (5%), and nausea (5%).

Malignancies: The overall frequency of malignancies was similar between adult RA patients treated with ORENCIA or placebo. However, more cases of lung cancer were observed in patients treated with ORENCIA (0.2%) than those on placebo (0%). A higher rate of lymphoma was seen compared to the general population; however, patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of ORENCIA in the development of malignancies in humans is unknown.

Most Frequent Adverse Events (≥10%): Headache, upper respiratory tract infection, nasopharyngitis, and nausea were the most commonly reported adverse events in the adult RA clinical studies. Other events reported in ≥5% of pJIA patients were diarrhea, cough, pyrexia, and abdominal pain. In general, the adverse events in pediatric pJIA and adult PsA patients were similar in frequency and type to those seen in adult RA patients. The most frequent adverse reactions of all grades reported in ≥10% of patients with aGVHD who received ORENCIA with a difference of ≥2% for the 7/8 cohort, 8/8 cohort Orencia arm, and 8/8 cohort placebo arm, respectively, were anemia (56%, 69%, and 57%), CD4 lymphocytes decreased (14%, 14%, and 9%), hypertension (49%, 43%, and 38%), pyrexia (28%, 19%, and 20%), CMV reactivation/CMV infection (26%, 32%,and 22%), pneumonia (19%, 12%, and 10%), epistaxis (12%, 16%, and 10%), acute kidney injury (9%, 15%, and 10%), and hypermagnesemia (5%, 18%, 10%).

Incidence rates of grade 3 or 4 adverse reactions were the same as incidence rates of all grades, with the exception of grade 3 or 4 pyrexia in all arms (9% [7/8 cohort], 10% [8/8 cohort, Orencia arm], and 4% [8/8 cohort, placebo arm]), pneumonia in the 8/8 cohort placebo arm (9%) and acute kidney injury in the 7/8 cohort Orencia arm (7%). Clinically relevant adverse reactions in <10% of patients who received ORENCIA in combination with calcineurin inhibitor and methotrexate in Study GVHD-1 included EBV reactivation.

Note concerning ORENCIA administration options: ORENCIA may be administered as an intravenous infusion only for patients 6 years of age and older. PJIA or pediatric PsA patients may self-inject with ORENCIA or the patient's caregiver may administer ORENCIA if both the healthcare practitioner and the parent/legal guardian determines it is appropriate. The ability of pediatric patients to self-inject with the autoinjector has not been tested. ORENCIA for the prophylaxis of aGVHD in patients undergoing HSCT may only be administered as an intravenous (IV) infusion. The safety and effectiveness of ORENCIA have not been established in pediatric patients younger than 2 years of age for prophylaxis of aGVHD.

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