

CODING AND BILLING GUIDE FOR ZILRETTA

Please see [Important Safety Information](#) throughout and accompanying full [Prescribing Information](#) for ZILRETTA.

 **Zilretta**[®]
triamcinolone acetonide extended release
injectable suspension 32 mg

CODING INFORMATION

At Flexion Therapeutics, we understand that coding and billing can be confusing and time-consuming. That's why with ZILRETTA® (triamcinolone acetonide extended-release injectable suspension), we're providing the simplicity of a medical benefit product with broad coverage and a permanent, product-specific J-code. We also offer you expertise and support services to give your practice a smooth experience.

The following codes may be appropriate when billing for ZILRETTA and related service.

ICD-10-CM Codes¹

M17.0	Bilateral primary osteoarthritis of knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

Permanent, Product-specific HCPCS Code²

	Description	Sites of Care	Billable Units
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	Physician office or hospital outpatient	Bill 32 units per injection (1 unit per mg)*

HCPCS=Healthcare Common Procedure Coding System.

*One ZILRETTA kit contains 32 mg of ZILRETTA, which should be billed as 32 units when using the permanent, product-specific J-code.

The information in this guide is general in nature and for informational purposes only. **In no way should this information be considered a guarantee of coverage or reimbursement for any product or service.** Coding and coverage policies change periodically, often without warning. The responsibility to determine coverage and reimbursement parameters and appropriate coding for a particular patient or procedure is always the responsibility of the provider.

CPT Code³

20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance	Used to report knee injections without ultrasound guidance
-------	---	--

CPT=Current Procedural Terminology.

Modifiers³

RT	Right side (used to identify procedures performed on the right side of the body)	Used to report injection in the right knee only
LT	Left side (used to identify procedures performed on the left side of the body)	Used to report injection in the left knee only
50	Bilateral procedure	Used to report injection in both knees

Hospital Revenue Codes (for hospital use only)⁴

0636	Drugs requiring detailed coding
0510	Clinic visit (general)

Product Information for ZILRETTA

11-digit NDC [†]	70801-0003-01
Drug strength and dose	32 mg triamcinolone acetonide ER

ER=extended-release; NDC=National Drug Code.

[†]11-digit NDC is derived from the 10-digit code for the ZILRETTA kit (70801-003-01). Keep in mind that many health plans require use of the 11-digit code.

INDICATION AND SELECT IMPORTANT SAFETY INFORMATION

Indication

ZILRETTA is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

Limitation of Use: The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

Contraindication

ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids, or any components of the product.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for ZILRETTA.



SAMPLE CMS-1500 CLAIM FORM: PHYSICIAN OFFICE

Practices that administer ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) to patients should submit claims on the CMS-1500 claim form or its electronic equivalent. Be sure to include the following information when filling out a CMS-1500 claim form.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

Box 21: M17.11

Box 23: [Submission Code]

Box 24D: J3304

Box 24E: RT

Box 24G: 32

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Box 21: Enter the appropriate ICD-10-CM diagnosis code corresponding to the patient's diagnosis, such as M17.11 (unilateral primary osteoarthritis, right knee)

Box 23: If required, report the Prior Authorization number here

Box 24D: Enter the permanent, product-specific J-code (J3304) to report the use of ZILRETTA. Also include the CPT code representing procedures performed (eg, 20610), as well as the appropriate modifier (ie, RT, LT, or 50)

Box 24E: Specify diagnosis from Box 21 relating to each CPT/HCPCS code listed in Box 24D

Box 24G: Enter the number of HCPCS units administered (bill 32 units of ZILRETTA per injection)

Please note that implementation time for the permanent, product-specific J-code may vary for commercial and Medicare Advantage plans. Contact FlexForward® to verify the appropriate codes to use when billing ZILRETTA.

This information is for reference only; please contact your patient's health plan or work with FlexForward to confirm coding for a specific plan

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. Serious events have been reported with epidural and intrathecal administration of corticosteroids and none are approved for this use. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- Hypersensitivity Reactions:** Rare instances of anaphylaxis, including serious cases, have occurred in patients with hypersensitivity to corticosteroids.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for ZILRETTA.



SAMPLE CMS-1450 CLAIM FORM: HOSPITAL OUTPATIENT

Providers administering ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) in an institutional setting, such as a hospital outpatient department, should use the CMS-1450 claim form (also known as UB-04) when coding and billing. Be sure to include the following information when filling out a CMS-1450 claim form.

Boxes

42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44

Box 44: Enter the permanent, product-specific J-code (J3304) to report the use of ZILRETTA. Also include the CPT code representing procedures performed (eg, 20610), as well as the appropriate modifier (ie, RT, LT, or 50)

Box 46: Enter the number of HCPCS units administered (bill 32 units of ZILRETTA per injection)

Box 63: If required, report the Prior Authorization number here

Box 66: Enter the appropriate ICD-10-CM diagnosis code corresponding to the patient's diagnosis, such as M17.11 (unilateral primary osteoarthritis, right knee)

Please note that implementation time for the permanent, product-specific J-code may vary for commercial and Medicare Advantage plans. Contact FlexForward® to verify the appropriate codes to use when billing ZILRETTA.

This information is for reference only; please contact your patient's health plan or work with FlexForward to confirm coding for a specific plan

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Joint Infection and Damage:** A marked increase in pain accompanied by local swelling, restriction of joint motion, fever, and malaise are suggestive of septic arthritis. Examine joint fluid to exclude a septic process. If diagnosis is confirmed, institute appropriate antimicrobial therapy. Avoid injecting corticosteroids into a previously infected or unstable joint. Intra-articular administration may result in damage to joint tissues.
- **Increased Risk of Infections:** Infection with any pathogen in any location of the body may be associated with corticosteroid use. Corticosteroids may increase the susceptibility to new infection and decrease resistance and the ability to localize infection.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for ZILRETTA.

Use J3304 and bill 32 units of ZILRETTA per injection



TIPS AND REMINDERS FOR SUBMITTING A CLAIM

Submitting claim forms

- Ensure all patient information (name, address, insurance ID) is accurate
- Verify the name of the healthcare provider and National Provider Identifier (NPI)
- Use the most appropriate ICD-10-CM diagnosis and CPT procedure codes associated with each patient's diagnosis and care
- Be sure to use the permanent, product-specific J-code (J3304) and bill 32 units of ZILRETTA **per injection**
- Complete all fields accurately and provide information upon request
- Contact provider services at the health plan to determine the reimbursement rate for ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) prior to billing and make sure your system is updated to bill appropriately

Additional documentation

- Ensure patient medical records contain documentation that supports the diagnosis and procedure codes submitted on the claim
- Keep in mind your practice may need to pull supporting documentation, such as patient history from the EMR
- Visit [ZilrettaPro.com/getting-zilretta/tools-and-resources/](https://zilretta.com/getting-zilretta/tools-and-resources/) for additional support with letters of medical necessity and appeals

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Alterations in Endocrine Function:** Corticosteroids can produce reversible hypothalamic-pituitary-adrenal axis suppression, with potential for adrenal insufficiency after withdrawal of treatment, which may persist for months. In situations of stress during that period, institute corticosteroid replacement therapy.
- **Cardiovascular and Renal Effects:** Corticosteroids can cause blood pressure elevation, salt and water retention, and increased potassium excretion. Monitor patients with congestive heart failure, hypertension, and renal insufficiency for edema, weight gain, and electrolyte imbalance. Dietary salt restriction and potassium supplementation may be needed.
- **Increased Intraocular Pressure:** Corticosteroid use may be associated with increased intraocular pressure. Monitor patients with elevated intraocular pressure for potential treatment adjustment.
- **Gastrointestinal Perforation:** Corticosteroid administration may increase the risk of gastrointestinal perforation in patients with certain GI disorders and fresh intestinal anastomoses. Avoid corticosteroids in these patients.
- **Alterations in Bone Density:** Corticosteroids decrease bone formation and increase bone resorption. Special consideration should be given to patients with or at increased risk of osteoporosis prior to treatment.
- **Behavior and Mood Disturbances:** Corticosteroids may cause adverse psychiatric reactions. Prior to treatment, special consideration should be given to patients with previous or current emotional instability or psychiatric illness. Advise patients to immediately report any behavior or mood disturbances.

Adverse Reactions

The most commonly reported adverse reactions (incidence $\geq 1\%$) in clinical studies included sinusitis, cough, and contusions.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#).

References: 1. ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-ICD-10-CM.html>. Updated January 27, 2020. Accessed February 7, 2020. 2. Quarterly Healthcare Common Procedure Coding System (HCPCS) drug/biological code changes – July 2018 update. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10624.pdf>. Updated April 20, 2018. Accessed February 7, 2020. 3. CPT code 20610 - 20605, 20600, 20611 - ICD - billing guide. Radiology Billing website. <http://www.radiologybillingcoding.com/2016/08/cpt-code-20610-billing-guide.html>. Updated May 30, 2018. Accessed February 7, 2020. 4. Revenue codes. Noridian Healthcare Solutions website. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>. Updated April 9, 2018. Accessed February 7, 2020.

For questions regarding coding and billing for ZILRETTA, contact your Flexion representative or call your dedicated FlexForward® Case Manager at 1-844-FLEXION (1-844-353-9466), Monday - Friday, 8 AM - 8 PM ET



COMPREHENSIVE SUPPORT WITH CODING AND BILLING

FlexForward[®]

• • • • • Comprehensive Access Support

Our dedicated team of Flexion representatives can provide your practice with national, regional, and local expertise to help address your coding and billing needs, including

- Tips on submitting a complete and accurate claim
- Information, training, and support to help navigate billing issues as they arise

This guide provides you with helpful information to assist you when coding and billing for ZILRETTA. The information in this guide is for reference only. Please contact your patient's health plan or work with FlexForward[®] to confirm coding for a specific plan.

To enroll your commercial and Medicare Advantage patients in FlexForward, simply complete a FlexForward[®] Enrollment Form available at ZilrettaPro.com/enrollment and fax it to **1-866-558-7939**

or

Contact your dedicated FlexForward Case Manager at **1-844-FLEXION (1-844-353-9466)**, Monday - Friday, 8 AM - 8 PM ET