

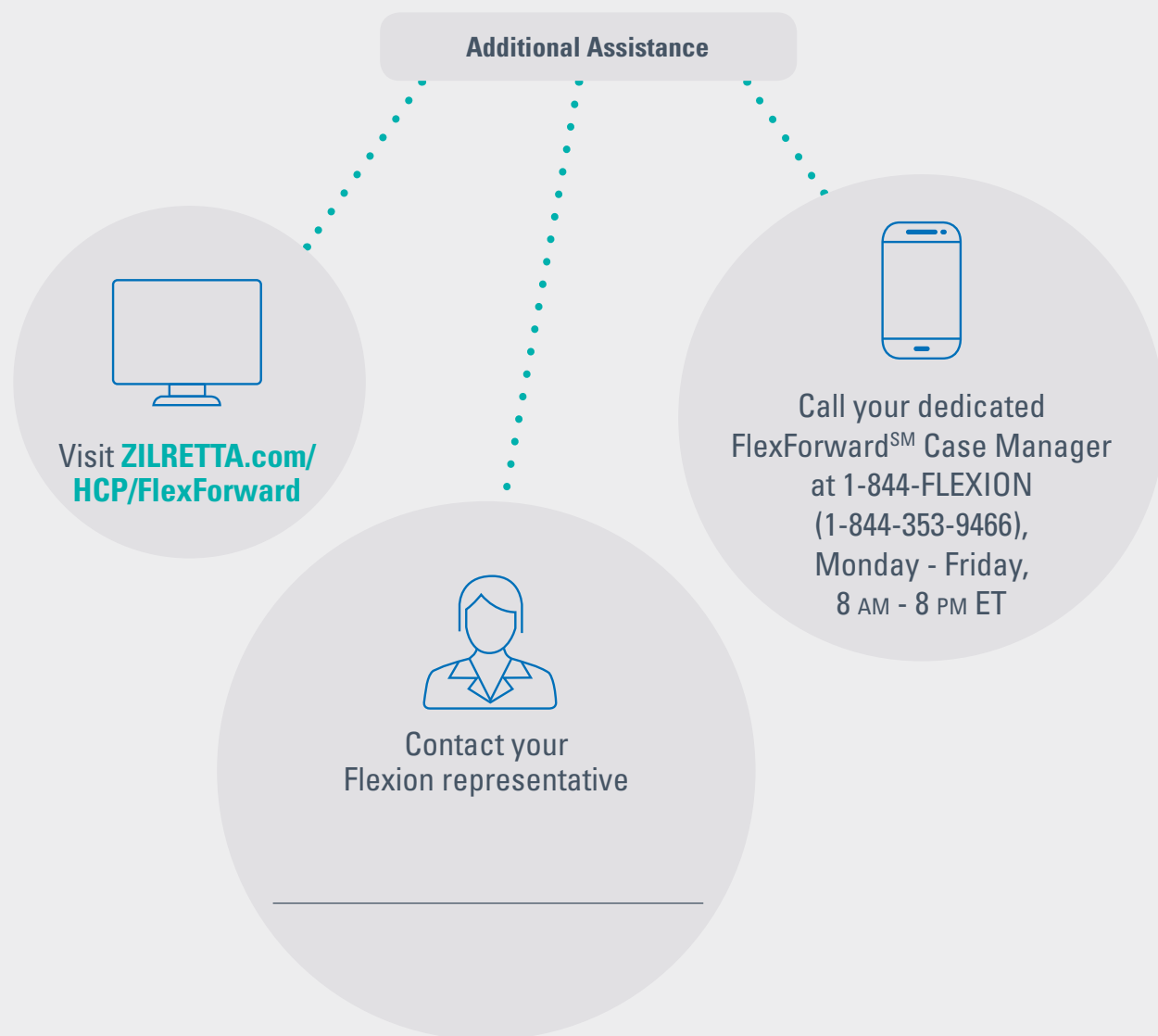
CODING AND BILLING GUIDE FOR ZILRETТА

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

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

SUPPORT WHEN YOU NEED IT

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 not just offering a treatment option for osteoarthritis knee pain. We also offer you expertise and support services to help you navigate a complex healthcare environment.



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.

COMPREHENSIVE SUPPORT WITH CODING AND BILLING

FlexForwardSM
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
- Insight into differences between commercial and Medicare insurance plans in your area
- Provide information, training, and support to help navigate billing issues, as they arise
- Verification of the appropriate codes to use based on your patient's insurance type

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 patient in FlexForward, please complete an enrollment form 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

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: ZILRETTA is not intended for repeat administration.*

Contraindication

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

*The efficacy and safety of repeat administration of ZILRETTA have not been evaluated.

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



CODING INFORMATION

The following codes may be appropriate when billing for ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) and related service.

ICD-10-CM Codes ¹	
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.

Product-specific HCPCS Code ²			
Q9993	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	Physician office or hospital outpatient for dates of service on or after July 1, 2018	Bill 32 units per injection (1 unit per mg)*

HCPCS=Healthcare Common Procedure Coding System.

Please note that some commercial and Medicare Advantage plans may require the use of the miscellaneous J-code (J3490) in the Physician Office and the product-specific C-code (C9469) in Hospital Outpatient Departments (HOPDs) or Ambulatory Surgery Centers (ASCs).^{3,4} Contact FlexForwardSM to verify the appropriate codes to use when billing for 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

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

CPT Code ⁵		
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.

Modifiers ⁵		
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) ⁶	
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.

[†]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.

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-1500 CLAIM FORM: PHYSICIAN OFFICE

Practices that administer ZILRETTA® (triamcinolone acetate 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: [blank]

1	24. A. DATE(S) OF SERVICE		24. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	24. E. DIAGNOSIS POINTERS	24. G. DAYS OR UNITS	24. J. RENDERING PROVIDER ID. #
	From	To				
1			Q9993	A	32	NPI
2			20610 RT	A	1	NPI
3						NPI
4						NPI
5						NPI
6						NPI

Box 24: Q9993, 20610 RT

Box 24E: A

Box 24G: 32, 1

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 Q-code (Q9993) to report the use of ZILRETTA until a permanent code is established. 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 NDC units administered. (When using the Q-code, bill 32 units of ZILRETTA for each injection)

Please note that some commercial and Medicare Advantage plans may require the miscellaneous J-code (J3490) in the Physician Office. Contact FlexForwardSM 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.



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 Q9993 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 NDC units administered. When using Q9993, bill 32 units of ZILRETTA for each 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 some commercial and Medicare Advantage plans may require the use of the product-specific C-code (C9469) in Hospital Outpatient Departments (HOPDs) or Ambulatory Surgery Centers (ASCs). Contact FlexForwardSM 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

- **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.

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



Effective for dates of service on and after July 1, 2018
Use Q9993 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
- Confirm the correct HCPCS code with your patient's health plan
- Bill the appropriate amount of units based on the code used
- 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 [ZILRETTA.com/HCP/ordering-and-access/tools-and-resources](https://www.zilretta.com/HCP/ordering-and-access/tools-and-resources) for additional support with letters of medical necessity and appeals

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

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **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](#) for ZILRETTA (triamcinolone acetonide extended-release injectable suspension).

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/2018-ICD-10-Table-And-Index.zip>. Updated August 11, 2017. Accessed May 3, 2018. 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 May 3, 2018. 3. 2018 table of drugs. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2018-Table-of-Drugs.pdf>. Updated February 15, 2018. Accessed May 9, 2018. 4. April 2018 update of the hospital outpatient prospective payment system (OPPS). Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10515.pdf>. Updated March 22, 2018. Accessed May 3, 2018. 5. CPT 20610 coding guidance. Noridian Healthcare Solutions website. <https://med.noridianmedicare.com/documents/10542/2840524/CPT+20610+Coding+Guidance/1d206be5-d097-45c3-a06a-c79c386c467d>. Updated September 2017. Accessed May 3, 2018. 6. Revenue codes. Noridian Healthcare Solutions website. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>. Updated November 3, 2017. Accessed May 3, 2018.





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