TRIESENCE® Suspension (triamcinolone acetonide injectable suspension) 40 mg/mL
Coding and Reimbursement Fact Sheet
NDC#00065-0543-01

TRIESENCE® Suspension Description and Indication
TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL is a preservative-free injectable suspension designed and approved for intraocular use in the United States, for treatment of uveitis, certain types of eye inflammation unresponsive to topical corticosteroids, sympathetic ophthalmia, and temporal arteritis. The drug is also approved for use in assisting with visualization during vitrectomy.

TRIESENCE® Suspension Diagnosis Codes
The majority of payors provide coverage for an injection of TRIESENCE® Suspension when used according to FDA label; however, few payors have established formal coverage policies outlining payable diagnosis codes. Payment, in most cases, is based on medical necessity.

Commonly covered diagnosis codes under the FDA label

<table>
<thead>
<tr>
<th>Diagnosis Description</th>
<th>Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sympathetic ophthalmia</td>
<td>360.11</td>
</tr>
<tr>
<td>Uveitis</td>
<td>360.11, 363.20, 364.00 and 364.3</td>
</tr>
<tr>
<td>Temporal arteritis</td>
<td>446.5</td>
</tr>
<tr>
<td>Ocular inflammatory conditions unresponsive to topical corticosteroids</td>
<td>Many diagnosis codes would apply to this condition Be prepared to demonstrate medical necessity including previous tried and failed topical corticosteroids prior to TRIESENCE® Suspension injection.</td>
</tr>
</tbody>
</table>

Since a number of diagnosis codes fall under the broad FDA indication of “ocular inflammatory conditions”, other diagnosis may meet the criteria for medical necessity. Document appropriate diagnosis codes and then check with the specific payor to determine if a topical corticosteroid must be administered prior to the injection of TRIESENCE® Suspension.

Because many carriers do not have written coverage policies that list covered diagnosis codes, most payors generally cover J3300 based on medical necessity.

For additional information about TRIESENCE® Suspension, please refer to the accompanying full prescribing information.
Billing Codes for TRIENCE® Suspension

Code: J3300- injection, triamcinolone acetonide, preservative free, 1 mg. (Effective January 1, 2009).

Units: TRIENCE® Suspension is a single dose vial containing 40 mg per mL and is reimbursed per vial, not per dose (mg). In order to receive correct reimbursement, providers must bill 40 mg.¹

Reimbursement

When the use of TRIENCE® Suspension is reasonable and necessary and is administered incident to a physician’s service, Medicare will provide coverage and reimbursement for the drug. For 2012 the Medicare reimbursement rate for separately payable drugs and biologicals is Average Sell Price (ASP) + 6%.

Effective January 2008, Medicare provides separate payment for non-pass-through drugs that are separately paid under OPPS when those drugs are integral to the performance of a covered procedure that is billed by the ASC. Prior to 2008, payment for a drug was bundled into the ASC payment rate.²

Commercial payor reimbursement will vary from payor to payor.

Coding and Reimbursement

<table>
<thead>
<tr>
<th>Code</th>
<th>J3300, Triamcinolone acetonide, preservative free, 1 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>* National Medicare Allowable</td>
<td>†Average Sale Price (ASP) + 6%</td>
</tr>
</tbody>
</table>

* For Medicare’s quarterly ASP updates go to http://www.cms.gov/McrPartBAvgSale
† Drug ASP files are updated quarterly and are available at https://www.cms.gov/McrPartBDrugAvgSalesPrice/.


For additional information about TRIENCE® Suspension, please refer to the accompanying full prescribing information.
**Physician Office**
Sample CMS - 1500 Paper Claim Form
TRIENSENCE® Suspension (triamcinolone acetonide injectable suspension) 40 mg/mL

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### Product and Procedure Information (Box 19):
Enter additional information including name, NDC code, and dosage TRIENSENCE® Suspension, 00065-0543-01, 40 mg/mL.

### Diagnosis Code (Box 21):
Enter appropriate ICD-9-CM diagnosis code(s) for example, 360.XX.

### Procedure Codes (Box 24D):
Enter CPT® codes that represent the procedures performed; for example, 67028, intravitreal injection of a pharmacologic agent.

### TRISENCE® Suspension:
TRISENCE® Suspension is a single dose drug. Bill 40 units.

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Information contained in this document is provided as a reference for providers in obtaining appropriate and accurate reimbursement. Content within the document is for information purposes only. Alcon does not guarantee that the use of the recommended codes will result in reimbursement. Providers may always contact the payer directly in regards to any reimbursement or billing questions.

CPT is a registered trademark of the American Medical Association.

For additional information about TRIENSENCE® Suspension, please refer to the accompanying full prescribing information.
<table>
<thead>
<tr>
<th><strong>1500</strong> HEALTH INSURANCE CLAIM FORM</th>
<th>NEPA</th>
<th>PECU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEDICARE</strong></td>
<td>NEPA</td>
<td>PECU</td>
</tr>
<tr>
<td><strong>MEDICAID</strong></td>
<td>NEPA</td>
<td>PECU</td>
</tr>
<tr>
<td><strong>TRIENESE® SUSPENSION</strong> (triamcinolone acetonide injectable suspension) 40 mg/mL</td>
<td>NEPA</td>
<td>PECU</td>
</tr>
<tr>
<td><strong>Sample CMS - 1500 Paper Claim Form</strong></td>
<td>NEPA</td>
<td>PECU</td>
</tr>
<tr>
<td><strong>Ambulatory Surgery Center</strong></td>
<td>NEPA</td>
<td>PECU</td>
</tr>
</tbody>
</table>

For additional information about TRIENESE® Suspension, please refer to the accompanying full prescribing information.

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For additional information about TRIENESE® Suspension, please refer to the accompanying full prescribing information.

| **Diagnosis Code (Box 21):** Enter appropriate ICD-9-CM diagnosis code(s); for example, 360.1 |
| **Modifiers (Box 24D):** Some payors may require that modifier -LT (left side) or -RT (right side) is appended to the CPT® code to indicate which eye received the treatment. |
| **Units (Box 24G):** TRIENESE® Suspension is a single dose drug. Bill 40 units. |
| **Product Codes (Box 24D):** For each CPT® code, insert the number for the corresponding diagnosis code from Block 21. |
TRIESENCE® Suspension (triamcinolone acetonide injectable suspension) 40 mg/mL

<table>
<thead>
<tr>
<th>Revenue Codes (Form Locator 42): Enter the revenue code that represents the procedure; for example, 360.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter the revenue code for TRIESENCE® Suspension; for Medicare use 636.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Codes (Form Locator 44): Enter the CPT® code the represents the procedure performed; for example, Vitrectomy, 67042.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some payors may require that modifier -LT (left side) or -RT (right side) is appended to the CPT® code to indicate which eye received the treatment. Modifiers are reported following the CPT® code in Form Locator 44.</td>
</tr>
</tbody>
</table>

| Product Codes (Form Locator 44): Enter code J3300, injection, triamcinolone acetonide, preservative free, 1 mg, to represent the use of TRIESENCE® Suspension. | 

| Units (Form Locator 46): TRIESENCE® Suspension is a single dose drug. Bill 40 units. | 

| Remarks (Form Locator 80): Enter additional product information including name, NDC code, and dosage; TRIESENCE® Suspension, 00065-0543-01, 40 mg/mL. | 

Information contained in this document is provided as a reference for providers in obtaining appropriate and accurate reimbursement. Content within the document is for information purposes only. Alcon does not guarantee that the use of the recommended codes will result in reimbursement. Providers may always contact the payer directly in regards to any reimbursement or billing questions. For additional information about TRIESENCE® Suspension, please refer to the accompanying full prescribing information.
HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL safely and effectively. See full prescribing information for TRIESENCE® suspension.

TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL

INDICATIONS AND USAGE

TRIESENCE® suspension is a synthetic corticosteroid indicated for:
- Treatment of the following ophthalmic diseases: sympathetic ophthalmia, temporal arteritis, uveitis, and scleral inflammatory conditions unresponsive to topical corticosteroids. (1.1)
- Visualization during vitrectomy. (1.2)

DOSAGE AND ADMINISTRATION

- Initial recommended dose for all indications except visualization: 4 mg (100 microliters of 40 mg/mL suspension) with subsequent dosage as needed over the course of treatment. (2.1)
- Recommended dose for visualization: 1 to 4 mg (25 to 100 microliters of 40 mg/mL suspension) administered intravitreally. (2.2)

DOSE FORMS AND STRENGTHS

Single use 1 mL vial containing 40 mg/mL of triamcinolone acetonide suspension. (3)

CONTRAINDICATIONS

- Patients with systemic fungal infections. (4)
- Hypersensitivity to triamcinolone or any component of this product. (4)
- **THESENCE** suspension should not be administered intravenously. (5.1)
- Ophthalmic effects: May include cataracts, infections, and glaucoma. Monitor intraocular pressure. (5.1)

WARNINGS AND PRECAUTIONS

- **THESENCE** suspension is a synthetic corticosteroid indicated for:
  - Treatment of the following ophthalmic diseases: sympathetic ophthalmia, temporal arteritis, uveitis, and scleral inflammatory conditions unresponsive to topical corticosteroids. (1.1)
  - Visualization during vitrectomy. (1.2)

DOSAGE AND ADMINISTRATION

- **STRICT ASEPTIC TECHNIQUE IS MANDATORY.**

2.1 Dosage for Treatment of Ophthalmic Diseases

- Initial recommended dose for all indications except visualization: 4 mg (100 microliters of 40 mg/mL suspension) with subsequent dosage as needed over the course of treatment. (2.1)
- Recommended dose for visualization: 1 to 4 mg (25 to 100 microliters of 40 mg/mL suspension) administered intravitreally. (2.2)

2.2 Dosage for Visualization during Vitrectomy

- The initial recommended dose of **THESENCE** suspension is 4 mg (100 microliters of 40 mg/mL suspension) with subsequent dosage as needed over the course of treatment. (2.2)
- The recommended dose of **THESENCE** suspension is 1 to 4 mg (25 to 100 microliters of 40 mg/mL suspension) administered intravitreally. (2.2)

2.3 Preparation for Administration

**STRICT ASEPTIC TECHNIQUE IS MANDATORY.** The vial should be vigorously shaken for 10 seconds before use to ensure a uniform suspension. Prior to withdrawal, the suspension should be inspected for clumping or granular appearance (sugaryation). An augmented product results from exposure to freezing temperatures and should not be used. After withdrawal, **THESENCE** suspension should be injected without delay to prevent settling in the syringe. Careful technique should be employed to avoid the possibility of streptococcal ocular infection and undesirable conditions unresponsive to topical corticosteroids.

2.4 Administration

The injection procedure should be carried out under aseptic conditions, including the use of sterile gloves, a sterile drape, and a sterile eye speculum (or equivalent). Adequate anesthesia and a broad-spectrum microbicide should be given prior to the injection. Following the injection, patients should be monitored for elevations in intraocular pressure and for endophthalmitis. Monitoring may consist of a check of the perfusion of the optic nerve head immediately after the injection, transitory within 10 minutes following the injection, and biannually between two and seven days following the injection. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eye speculum, and injection needles should be changed before **THESENCE** suspension is administered to the other eye.

3 DOSAGE FORMS AND STRENGTHS

Single use 1 mL vial containing 40 mg/mL of triamcinolone acetonide suspension. (3)

CONTRAINDICATIONS

- **THESENCE** suspension should not be administered intravenously. (5.1)

4 DRUG INTERACTIONS

Antibiotic agents: May enhance or diminish an antiarrhythmic effect. (7)

5 WARNINGS AND PRECAUTIONS

- Behavioral and mood disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis. (5.6)
- Decreases in bone density: Monitor bone density in patients receiving long-term corticosteroid therapy. (5.7)
- Live or live attenuated vaccines: Do not administer to patients receiving immunosuppressive doses of corticosteroids. (5.8)
- Negative effects on growth and development: Monitor pediatric patients on long-term corticosteroid therapy. (5.9)
- Use in pregnancy: Fetal harm can occur with first trimester use. (5.10)
- Weight gain: May cause increased appetite. (5.11)

5.11 Weight Gain

5.12 Hormonal Effects

5.13 Reproductive System

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.3 Nursing Mothers

8.4 Pediatric Use

8.5 Geriatric Use

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

13 NONCLINICAL TOXICOLOGY

13.2 Animal Toxicology and/or Pharmacology

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

Full Prescribing Information: Contents*
5.2 Alterations in Endocrine Function
Hypercorticalism (or Cushing’s syndrome) occurs with long-term corticosteroid therapy, particularly when high doses are used. Corticosteroids cause a suppression of endogenous ACTH and the pituitary-gonadal axis. They also cause hyperglycemia, osteoporosis, and muscle wasting.

5.3 Increased Risks Related to Infections
Corticosteroids may lower the resistance to infection in patients with acute or chronic infections. They may also impair the host's ability to recognize a foreign agent. Some studies have shown that oral corticosteroids may actually increase the severity of infections.

5.4 Behavioral and CNS Effects
Corticosteroids may cause mood changes, irritability, restlessness, nervousness, or insomnia. In rare cases, they may cause symptoms of psychotic behavior, delusions, hallucinations, or mania. These effects are more common in children and the elderly.

5.5 Maternal and Fetal Effects
Corticosteroids can cross the placental barrier and may cause premature closure of the ductus arteriosus in the newborn. They can also cause decreased birth weight. If this drug is used during pregnancy, or if the patient becomes pregnant while using this drug, the patient should be informed of the potential risk to the fetus.

6 Adverse Reactions

6.1 Drug Interactions
Corticosteroids can interact with many other drugs, potentially increasing or decreasing their effects. Some examples include:

- **Anticoagulants**: The use of corticosteroids may reduce the effectiveness of anticoagulants, increasing the risk of thromboembolic events.
- **Digitalis glycosides**: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.
- **Cyclosporine**: Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported in patients taking both medications.
- **Amphotericin B**: There are reports of increased risk of myocardial toxicity when corticosteroids are used concomitantly with amphotericin B.
- **Amphoterics**: The use of corticosteroids may increase the risk of infection in patients on these medications.
- **Bacterial, fungal, or viral infections**: Corticosteroids may increase the risk of infections in patients with a history of such infections.
- **Carcinogenesis, mutagenesis, andimpairment of fertility**: Corticosteroids can impair fertility in both men and women.
- **Osteoporosis**: Corticosteroids can increase the risk of osteoporosis in patients on long-term therapy.
- **Hypokalemia**: Increased risk of hypokalemia in patients taking potassium-depleting agents.
- **Increased risk of Cushing's syndrome**: Corticosteroids can cause Cushing's syndrome, which is characterized by weight gain, moon facies, and buffalo hump.

7 DRUG INTERACTIONS

8.1 Teratogenic Effects
Animal studies have shown that corticosteroids can cause embryonic and fetal abnormalities. Corticosteroids can cause abortions, stillbirths, and congenital anomalies. In humans, the risk of congenital anomalies is increased in patients taking corticosteroids during the first trimester.

9.2 Pregnancy
Corticosteroids can cause fetal harm when administered to a pregnant woman. Corticosteroids should be avoided in pregnant women, particularly during the first trimester, to prevent complications such as premature birth.

10.1 Oral Contraceptives
Corticosteroids can decrease the effectiveness of oral contraceptives. Patients taking oral contraceptives should be advised to use alternative forms of birth control.

11.5 Effects on Children
Corticosteroids are generally considered safe for children, but may cause growth suppression in children taking high doses for prolonged periods.

12.2 Precautions
Corticosteroids should be used with caution in patients with a history of peptic ulcer disease, because they can cause an increase in stomach acid production.

13.3 Administration
Corticosteroids are generally well tolerated, but some patients may experience side effects such as fluid retention, weight gain, and mood changes.

14.1 Pregnancy
Corticosteroids can cause fetal harm when administered to a pregnant woman. Corticosteroids should be avoided in pregnant women, particularly during the first trimester, to prevent complications such as premature birth.

15.5 Evaluation
The adverse effects of corticosteroids in pediatric patients are similar to those in adults. [See Adverse Reactions (6)].
11 DESCRIPTION
TRIENSE® (triamcinolone acetonide injectable suspension) 40 mg/mL is a synthetic corticosteroid with anti-inflammatory action. Each mL of the sterile, aqueous suspension provides 40 mg triamcinolone acetonide, with sodium chloride for isotonicity, 0.5% (w/v) carboxymethylcellulose and 0.015% polysorbate-80 in a balanced salt solution. Sodium hydroxide and hydrochloric acid may be present to adjust pH to a target value 6 – 7.5.

The chemical name for triamcinolone acetonide is 9-Fluro-11,16,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17- acetal with acetone. Its structural formula is:

\[
\begin{align*}
\text{HO} & \\
\text{CH} & \\
\text{HO} & \\
\text{CH}_3 & \\
\end{align*}
\]

434.50 MW

Triamcinolone acetonide occurs as a white to cream-colored, crystalline powder having not more than a slight odor and is practically insoluble in water and very soluble in alcohol.

12 CLINICAL PHARMACOLOGY
Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenal insufficiency. Their synthetic analogs such as prednisolone and triamcinolone are primarily used for their anti-inflammatory effects in disorders of many organ systems. Triamcinolone acetonide possesses glucocorticoid activity typical of this class of drug, but with little or no mineralocorticoid activity. The purpose of comparison, the following is the equivalent dosage of the various glucocorticoids:

| Cortisone, 25 | Prednisolone, 5 | Paramethesone, 2 |
| Hydrocortisone, 20 | Methylprednisolone, 4 | Betamethasone, 0.75 |
| Prednisolone, 5 | Triamcinolone, 4 | Dexamethasone, 0.75 |

Corticosteroids have been demonstrated to depress the production of eosinophils and lymphocytes, but myelopoiesis and production of polymorphonuclear leukocytes are stimulated. Inflammatory processes (edema, fibrin deposition, capillary dilatation, migration of leukocytes and phagocytes) and the later stages of wound healing (capillary proliferation, deposition of collagen, scar formation) are inhibited.

12.1 Mechanism of Action

Corticosteroids have been demonstrated to depress the production of eosinophils and lymphocytes, but myelopoiesis and production of polymorphonuclear leukocytes are stimulated. Inflammatory processes (edema, fibrin deposition, capillary dilatation, migration of leukocytes and phagocytes) and the later stages of wound healing (capillary proliferation, deposition of collagen, scar formation) are inhibited.