



Harrow Announces Transitional Pass-Through Reimbursement Status for TRIESENCE® (Triamcinolone Acetonide Injectable Suspension) 40 mg/mL

March 24, 2025

NASHVILLE, Tenn.--(BUSINESS WIRE)--Mar. 24, 2025-- Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, today announced that the Centers for Medicare & Medicaid Services (CMS) has approved Harrow's transitional pass-through application for TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL, a preservative-free synthetic corticosteroid that is approved by the U.S. Food and Drug Administration (FDA) for visualization during vitrectomy and for the treatment of ocular inflammatory conditions that are unresponsive to topical corticosteroids.

Beginning April 1, 2025, and for the three years thereafter, TRIESENCE will be eligible for separate reimbursement outside of the surgical bundled payment in both the Ambulatory Surgery Center (ASC) and Hospital Outpatient Department (HOPD) settings of care. CMS previously approved the issuance of a permanent, product-specific J-Code (J3300) for TRIESENCE, facilitating reimbursement and access in eyecare professionals' offices. With this new CMS approval, TRIESENCE becomes the only preservative-free synthetic corticosteroid with separate reimbursement in all traditional settings of care – the eyecare professional's office, the ASC, and the HOPD. CMS will now separately reimburse TRIESENCE at the Average Sales Price (ASP) plus 6% in both ASC and HOPD settings.

"We sincerely appreciate CMS's approval of pass-through reimbursement status for TRIESENCE, recognizing its unique value to ophthalmic care," said Mark L. Baum, Chairman and Chief Executive Officer of Harrow. "Following Harrow's investment in the restoration of the TRIESENCE supply chain, this decision expands patient access to TRIESENCE, allowing all ophthalmologists, including retina specialists, to return confidently to using an FDA-approved, preservative-free treatment option in lieu of the more dangerous, off-label options they had been forced to use while TRIESENCE was unavailable. This news, which allows for the reimbursement of TRIESENCE in a critical setting of care, increases access to all Medicare beneficiaries and should improve surgical outcomes and patient safety across the country."

Billing and Ordering TRIESENCE

TRIESENCE (J3300 Injection, triamcinolone acetonide, preservative-free, 1 mg) is a single-use vial of 40 milligrams or 40 units based on the HCPCS descriptor.

Healthcare providers may order TRIESENCE directly through major pharmaceutical specialty distributors, including Besse Medical/Cencora, McKesson/McKesson Medical-Surgical, and Cardinal Health/Cardinal Specialty/Metro Medical. TRIESENCE is currently listed under both NDC 00078-0897-78 and NDC 82667-0800-01. Additional information about TRIESENCE can be found at [TRIESENCEHCP.com](https://www.triesencehcp.com).

About Harrow

Harrow, Inc. (Nasdaq: HROW) is a leading eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic pharmaceutical products for the North American market. Harrow helps eyecare professionals preserve the gift of sight by making its portfolio of pharmaceutical products accessible and affordable to millions of patients each year. For more information about Harrow, please visit [harrow.com](https://www.harrow.com).

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward-looking statements." Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include, among others, risks related to: liquidity or results of operations; our ability to successfully implement our business plan, develop and commercialize our products, product candidates and proprietary formulations in a timely manner or at all, identify and acquire additional products, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions, including inflation and supply chain challenges; regulatory and legal risks, including litigation matters, and other uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general;

physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally. These and additional risks and uncertainties are more fully described in Harrow's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2023, subsequent Quarterly Reports on Form 10-Q, and other filings with the SEC. Such documents may be read free of charge on the SEC's web site at [sec.gov](https://www.sec.gov). Undue reliance should not be placed on forward looking statements, which speak only as of the date they are made. Except as required by law, Harrow undertakes no obligation to update any forward-looking statements to reflect new information, events, or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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

HIGHLIGHTS OF TRIESENCE PRESCRIBING INFORMATION

INDICATIONS AND USAGE

TRIESENCE suspension is a synthetic corticosteroid indicated for:

- Treatment of the following ophthalmic diseases: sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.
- Visualization during vitrectomy.

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.
- Recommended dose for visualization: 1 to 4 mg (25 to 100 microliters of 40 mg/mL suspension) administered intravitreally.

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

- Patients with systemic fungal infections.
- Hypersensitivity to triamcinolone or any component of this product.

WARNINGS AND PRECAUTIONS

- TRIESENCE suspension should not be administered intravenously.
- Ophthalmic effects: May include cataracts, infections, and glaucoma. Monitor intraocular pressure.
- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome and hyperglycemia: Monitor patients for these conditions and taper doses gradually.
- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination, or reactivation of latent infection.
- Elevated blood pressure, salt and water retention, and hypokalemia: Monitor blood pressure and sodium, potassium serum levels.
- GI perforation: Increased risk in patients with certain GI disorders.
- Behavioral and mood disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis.
- Decreases in bone density: Monitor bone density in patients receiving long-term corticosteroid therapy.
- Live or live attenuated vaccines: Do not administer to patients receiving immunosuppressive doses of corticosteroids.
- Negative effects on growth and development: Monitor pediatric patients on long-term corticosteroid therapy.
- Use in pregnancy: Fetal harm can occur with first trimester use.
- Weight gain: May cause increased appetite.

DRUG INTERACTIONS

- Anticoagulant agents: May enhance or diminish anticoagulant effects. Monitor coagulation indices.
- Antidiabetic agents: May increase blood glucose concentrations. Dose adjustments of antidiabetic agents may be required.
- CYP 3A4 inducers and inhibitors: May respectively increase or decrease clearance of corticosteroids necessitating dose adjustment.
- Non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and salicylates: Increased risk of gastrointestinal side effects.

For complete product information about TRIESENCE, including important safety information, please visit: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3f045347-3e5e-4bbd-90f8-6c3100985ca5>

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