

## Xipere<sup>®</sup> (triamcinolone acetonide injectable suspension)

### (Suprachoroidal)

Document Number: IC-0633

Last Review Date: 08/08/2023

Date of Origin: 12/02/2021

Dates Reviewed: 12/2021, 04/2022, 07/2022, 09/2022, 08/2023

### I. Length of Authorization

Coverage will be provided for 12 weeks and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Xipere 36 mg/0.9 mL (40 mg/mL concentration) single-dose vial: 2 vials every 12 weeks

#### B. Max Units (per dose and over time) [HCPCS Unit]:

- 72 billable units (72 mg; 2 vials) every 12 weeks

*(Quantity Limits/Max Units are based on administration to BOTH eyes)*

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

#### Universal Criteria <sup>1,3</sup>

- Patient is free of ocular and periocular infections, including but not limited to, active epithelial herpes simplex keratitis; **AND**
- Patient has not received any of the following sustained-release intravitreal corticosteroids:
  - Dexamethasone – within the prior 4 months (i.e., Ozurdex<sup>®</sup>)
  - Fluocinolone acetonide – within the prior 30 months (i.e., Retisert<sup>®</sup>) or 36 months (i.e., Iluvien<sup>®</sup>/Yutiq<sup>™</sup>); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient does not have untreated intraocular pressure or uncontrolled glaucoma; **AND**

#### Macular Edema † <sup>1-3</sup>

- Patient has macular edema related to a diagnosis of non-infectious uveitis (pan, anterior, intermediate, and/or posterior)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cataracts, increase in intraocular pressure, glaucoma, alterations in endocrine function (e.g., hypothalamic-pituitary-adrenal [HPA] axis suppression, Cushing’s syndrome, hyperglycemia), etc.; **AND**
- Disease response as indicated by stabilization of visual acuity or improvement in best-corrected visual acuity (BCVA) score when compared to baseline.

#### V. Dosage/Administration <sup>1</sup>

| Indication  | Dose   |
|---|--|
| Macular Edema Secondary to Non-Infectious Uveitis | <ul style="list-style-type: none"> <li>• Administer Xipere (triamcinolone acetonide injectable suspension) as a suprachoroidal injection using the SCS Microinjector®.</li> <li>• The recommended dose of Xipere is 4 mg (0.1 mL of the 40 mg/mL injectable suspension) and may be repeated every 12 weeks.</li> <li>• <b>Note:</b> Xipere is available as a 36mg/0.9mL single-dose vial (40 mg/mL concentration)</li> </ul> |

#### VI. Billing Code/Availability Information

HCPCS code:

- J3299 – Injection, triamcinolone acetonide (xipere), 1 mg; 1 billable unit = 1 mg

NDC:

- Xipere 36 mg/0.9 mL (40 mg/mL concentration) injectable suspension single-dose vial: 24208-0040-xx

#### VII. References

1. Xipere [package insert]. Bridgewater, NJ; Bausch & Lomb Americas Inc.; September 2022. Accessed July 2023.
2. Yeh S, Kurup SK, Wang RC, et al for the DOGWOOD Study Team. Suprachoroidal injection of triamcinolone acetonide, CLS-TA, for macular edema due to noninfectious uveitis - A

Randomized, Phase 2 Study (DOGWOOD). Retina: Oct2019;39,10;1880-1888. doi: 10.1097/IAE.0000000000002279.

3. Yeh S, Khurana RN, Shah M, et al; PEACHTREE Study Investigators. Efficacy and Safety of Suprachoroidal CLS-TA for Macular Edema Secondary to Noninfectious Uveitis: Phase 3 Randomized Trial. Ophthalmology. 2020 Jul;127(7):948-955. doi: 10.1016/j.ophtha.2020.01.006.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10  | Diagnosis   |
|---------|---|
| H30.001 | Unspecified focal chorioretinal inflammation right eye                    |
| H30.002 | Unspecified focal chorioretinal inflammation left eye                     |
| H30.003 | Unspecified focal chorioretinal inflammation bilateral                    |
| H30.009 | Unspecified focal chorioretinal inflammation unspecified eye              |
| H30.011 | Focal chorioretinal inflammation, juxtapapillary right eye                |
| H30.012 | Focal chorioretinal inflammation, juxtapapillary left eye                 |
| H30.013 | Focal chorioretinal inflammation, juxtapapillary bilateral                |
| H30.019 | Focal chorioretinal inflammation, juxtapapillary unspecified eye          |
| H30.021 | Focal chorioretinal inflammation of posterior pole right eye              |
| H30.022 | Focal chorioretinal inflammation of posterior pole left eye               |
| H30.023 | Focal chorioretinal inflammation of posterior pole bilateral              |
| H30.029 | Focal chorioretinal inflammation of posterior pole unspecified eye        |
| H30.031 | Focal chorioretinal inflammation, peripheral right eye                    |
| H30.032 | Focal chorioretinal inflammation, peripheral left eye                     |
| H30.033 | Focal chorioretinal inflammation, peripheral bilateral                    |
| H30.039 | Focal chorioretinal inflammation, peripheral unspecified eye              |
| H30.041 | Focal chorioretinal inflammation, macular or paramacular right eye        |
| H30.042 | Focal chorioretinal inflammation, macular or paramacular left eye         |
| H30.043 | Focal chorioretinal inflammation, macular or paramacular bilateral        |
| H30.049 | Focal chorioretinal inflammation, macular or paramacular unspecified eye  |
| H30.101 | Unspecified disseminated chorioretinal inflammation right eye             |
| H30.102 | Unspecified disseminated chorioretinal inflammation left eye              |
| H30.103 | Unspecified disseminated chorioretinal inflammation bilateral             |
| H30.109 | Unspecified disseminated chorioretinal inflammation unspecified eye       |
| H30.111 | Disseminated chorioretinal inflammation of posterior pole right eye       |
| H30.112 | Disseminated chorioretinal inflammation of posterior pole left eye        |
| H30.113 | Disseminated chorioretinal inflammation of posterior pole bilateral       |
| H30.119 | Disseminated chorioretinal inflammation of posterior pole unspecified eye |
| H30.121 | Disseminated chorioretinal inflammation, peripheral right eye             |

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| ICD-10  | Diagnosis  |
|---------|--|
| H30.122 | Disseminated chorioretinal inflammation, peripheral left eye         |
| H30.123 | Disseminated chorioretinal inflammation, peripheral bilateral        |
| H30.129 | Disseminated chorioretinal inflammation, peripheral unspecified eye  |
| H30.131 | Disseminated chorioretinal inflammation, generalized right eye       |
| H30.132 | Disseminated chorioretinal inflammation, generalized left eye        |
| H30.133 | Disseminated chorioretinal inflammation, generalized bilateral       |
| H30.139 | Disseminated chorioretinal inflammation, generalized unspecified eye |
| H30.90  | Unspecified chorioretinal inflammation unspecified eye               |
| H30.91  | Unspecified chorioretinal inflammation right eye                     |
| H30.92  | Unspecified chorioretinal inflammation left eye                      |
| H30.93  | Unspecified chorioretinal inflammation bilateral                     |
| H35.81  | Retinal edema  |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |
|---|---|---|
| Jurisdiction  | Applicable State/US Territory   | Contractor  |
| E (1)   | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |
| 5   | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6   | MN, WI, IL  | National Government Services, Inc. (NGS)          |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)  | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| L (12)  | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |
| 15  | KY, OH  | CGS Administrators, LLC                           |

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