

Drug Class Review Monograph – GPI Class 22 – Corticosteroids

Review Time Frame: 05/2016 – 04/2017 Previous Class Review: N/A

Background:

Corticosteroid drugs, which include cortisone, hydrocortisone, methylprednisolone, prednisolone, and prednisone, are useful for treating many conditions, such as rashes, lupus, rheumatoid arthritis, allergies, and asthma.

Corticosteroids mimic the effects of hormones produced naturally in the adrenal glands, which sit on top of the kidneys. When prescribed in doses that exceed the body's usual levels, corticosteroids suppress inflammation. This can reduce the signs and symptoms of inflammatory conditions, such as arthritis and asthma.

Corticosteroids also suppress the immune system, which can help control conditions in which the immune system mistakenly attacks its own tissues.

New treatment guideline recommendations:

• None identified

Newly approved drugs:

• Approved 02/09/2017: Emflaza (deflazacort) 22.75 mg/mL oral suspension and 6 mg, 18 mg, 30 mg, and 36 mg tablets; currently commercially available.

Newly approved formulations:

• None identified

Newly approved generics:

• None identified

Discontinued drugs:

• None identified

FDA Safety Alerts/black box warnings:

• None identified

Pipeline alerts:

Agents pending FDA approval include:

- Dextenza (dexamethasone sustained-release), an intraocular implant proposed for the treatment of ocular pain following ophthalmic surgery; PDUFA: 07/19/2017.
- Silretta (triamcinolone sustained-release), an intra-articular injection proposed for the treatment of pain associated with osteoarthritis of the knee; PDUFA: 10/06/2017.
- Resolve (mometasone), a steroid-releasing implant proposed for the treatment of chronic sinusitis; PDUFA: 01/08/2018.



• Dexycu (dexamethasone extended-release), an intraocular injection proposed for the treatment of inflammation associated with cataract surgery; PDUFA: 02/13/2018.

References:

- 1. Nieman LK. Pharmacologic use of glucocorticoids. Lacroix, A. (Ed), UpToDate. Waltham MA. Accessed April 2016.
- 2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. URL: http://www.clinicalpharmacology-ip.com/. Accessed May 2017.
- 3. US Script Oracle PBM: Medi-Span[®] Master Drug Data Base. April 2016.
- 4. Food and Drug Administration. <u>WWW.FDA.GOV</u>. Accessed May 2017.
- 5. Envolve Pharmacy Solutions internal pipeline database. Accessed May 2017.