

# Updates to the Specialty Drug List for May 2020

## Drugs added to the Specialty Offering that will not be dispensed via Accredo:

### Fensolvi

On May 1, 2020, the FDA approved Fensolvi<sup>®</sup> (leuprolide acetate) to treat pediatric patients 2 years of age and older with central precocious puberty. It is being launched through a network of specialty pharmacies that does not include Accredo.

### Isturisa

On March 6, 2020, the FDA approved Isturisa<sup>®</sup> (osilodrostat) to treat adult patients who have Cushing's disease and for whom pituitary surgery is not an option or has not been curative. It is being launched through a network of specialty pharmacies that does not include Accredo.

### Pemazyre

On April 17, 2020, the FDA approved Pemazyre<sup>™</sup> (pemigatinib) to treat adult patients who have previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. It is being launched through a network of specialty pharmacies that does not include Accredo.

### Romidepsin

On March 13, 2020, the FDA approved Teva's romidepsin, which is neither generic for nor interchangeable with Istodax<sup>®</sup>. Romidepsin is indicated to treat adults who have had one or more previous treatments for cutaneous or peripheral T-cell lymphoma. It is available through open distribution, however a business decision was made not to dispense it.

### Trodelvy

On April 22, 2020, the FDA approved Trodelvy<sup>™</sup> (sacituzumab govitecan-hziy) to treat adult patients who have metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. It will not be available to specialty pharmacies.

### Tukysa

On April 17, 2020, the FDA approved Tukysa<sup>™</sup> (tucatinib) for use in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. It is being launched through a network of specialty pharmacies that does not include Accredo.

## Definition of a Specialty Drug:

Specialty drugs, which can be given by any route of administration and are typically used to treat chronic, complex conditions, are defined as having one more of several key characteristics, including:

1. The requirement for frequent dosing adjustments and intensive clinical monitoring to decrease the potential for drug toxicity and increase the probability for beneficial treatment outcomes
2. The need for intensive patient training and compliance assistance to facilitate therapeutic goals
3. Limited or exclusive specialty pharmacy distribution
4. Specialized product handling and/or administration requirements