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PHARMNOTES

November 2023

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Pharmacy Benefit Management
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Drug Safety Alert Notification

- No drug safety communication published in November.

New FDA-Approved Drug Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
FRUZAQLA™ (FRUQUINTINIB) CAPSULES FOR ORAL USE	TAKEDA PHARMACEUTICALS, INC.	11/08/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

DOSAGE AND ADMINISTRATION
- The recommended dose of is 5 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity. Take with or without food at approximately the same time each day.
- Swallow capsule whole
- The recommended dose reductions for adverse effects are:
  - First dose reduction: 4 mg orally once daily
  - Second dose reduction: 3 mg orally once daily
  - Permanently discontinue in patients unable to tolerate 3 mg orally once daily.

DOSAGE FORMS AND STRENGTHS
Capsules: 1 mg and 5 mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- *Hypertension*: Control blood pressure prior to treatment and monitor during treatment. Manage with anti-hypertensive medications and adjustment of the dose of Fruzaqla™, if necessary. Withhold, dose reduce, or permanently discontinue based on severity of hypertension.
- *Hemorrhagic Events*: Closely monitor patients who are at risk for bleeding. Withhold, reduce dose, or permanently discontinue Fruzaqla™ based on severity and persistence of hemorrhage.
- *Infections:* Monitor for infection during treatment and withhold Fruzaqla™ during active infections. Do not start Fruzaqla™ in patients with active infections
- *Gastrointestinal (GI) Perforation:* Periodically monitor for GI perforation. Permanently discontinue Fruzaqla™ in patients who develop GI perforation or fistula.
- *Hepatotoxicity:* Monitor liver laboratory tests prior to the start of Fruzaqla™ and periodically during treatment. Withhold, reduce the dose, or permanently discontinue based on severity.
- *Proteinuria:* Monitor urine protein. Discontinue Fruzaqla™ for nephrotic syndrome.
- *Palmar-Plantar Erythrodysesthesia:* Withhold Fruzaqla™ based on severity.
- *Posterior Reversible Encephalopathy Syndrome (PRES)*: Immediately discontinue Fruzaqla™ if PRES is suspected and confirmed via Magnetic Resonance Imaging (MRI).
- *Impaired Wound Healing*: Withhold Fruzaqla™ for 2 weeks before major surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of Fruzaqla™ after resolution of wound healing complications has not been established.
- *Arterial Thromboembolic Events*: Initiation of Fruzaqla™ in patients with a recent history of thromboembolic events should be carefully considered. Discontinue Fruzaqla™ in patients who develop arterial thromboembolism.
- *Allergic Reactions to FD&C Yellow No. 5 (Tartrazine) and No. 6 (Sunset Yellow FCF):* Contains FD&C Yellow No. 5 and No. 6 as color additives, which may cause allergic reactions (including bronchial asthma) in certain susceptible patients.
- *Embryo-Fetal Toxicity:* Can cause fetal harm. Advise patients of reproductive potential of the potential risk to the fetus and to use effective contraception.

DRUG NAME	MANUFACTURER	APPROVAL DATE
FRUZAQLA™ (FRUQUINTINIB) CAPSULES FOR ORAL USE	TAKEDA PHARMACEUTICALS, INC.	11/08/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

DOSAGE AND ADMINISTRATION
- The recommended dose of is 5 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity. Take with or without food at approximately the same time each day.
- Swallow capsule whole
- The recommended dose reductions for adverse effects are:
  - First dose reduction: 4 mg orally once daily
  - Second dose reduction: 3 mg orally once daily
  - Permanently discontinue in patients unable to tolerate 3 mg orally once daily.

DOSAGE FORMS AND STRENGTHS
Capsules: 1 mg and 5 mg

Orphan status: No

SAFETY PROFILE

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥20%) are hypertension, palmar-plantar erythrodysesthesia, proteinuria, dysphonia, abdominal pain, diarrhea, and asthenia.

DRUG INTERACTIONS
- *Strong CYP3A4 Inducers:* Avoid concomitant use.
- *Moderate CYP3A4 Inducers:* If possible, avoid concomitant use. If not possible to avoid concomitant use, continue to administer Fruzaqla™ at the recommended dosage.

USE IN SPECIFIC POPULATION
- *Pregnancy:* Based on its mechanism of action, Fruzaqla™ can cause fetal harm when administered to a pregnant woman.
- *Lactation*: Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed during treatment and for 2 weeks after the last dose.
- *Females and Males of Reproductive Potential*: Verify the pregnancy status of females of reproductive potential prior to initiating treatment. Advise females of reproductive potential and males with female partners of childbearing potential to use effective contraception during treatment with Fruzaqla™ and for 2 weeks after the last dose.

DRUG NAME	MANUFACTURER	APPROVAL DATE
ADZYNMA (ADAMTS13, RECOMBINANT-KRHN) LYOPHILIZED POWDER FOR INJECTION, FOR INTRAVENOUS USE	TAKEDA PHARMACEUTICALS, INC.	11/09/2023

THERAPEUTIC CLASS
Enzyme replacement therapy

FDA-APPROVED INDICATION(S)
Indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP)

DOSAGE AND ADMINISTRATION
Prophylactic Therapy:
- Administer 40 IU/kg body weight once every other week intravenously at a rate of 2 to 4 mL per minute.
- The prophylaxis dosing frequency may be adjusted to 40 IU/kg body weight once weekly based on prior prophylactic dosing regimen or clinical response

On-Demand therapy:
- 40 IU/kg body weight on day 1.
- 20 IU/kg body weight on day 2.
- 15 IU/kg body weight on day 3 and beyond until two days after the acute event is resolved.

DOSAGE FORMS AND STRENGTHS
Adzynma™ is available as a lyophilized powder in single-dose vials containing nominally 500 or 1500 international units.

SAFETY PROFILE

CONTRAINDICATIONS
- Do not use in patients who have manifested life threatening hypersensitivity reactions to Adzynma™ or its components.

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions may occur. Discontinue Adzynma™ if hypersensitivity symptoms occur and administer appropriate emergency treatment.
- *Immunogenicity:* Patients may develop antibodies to rADAMTS13 which could potentially result in a decreased or lack of response to rADAMTS13. Patients may develop antibodies to host cell proteins which could potentially result in adverse reactions. There are no data on risk in previously untreated patients (subjects naïve to plasmabased products).

ADVERSE REACTIONS
- Most common adverse reactions (incidence >5%) are headache, diarrhea, migraine, abdominal pain, nausea, upper respiratory tract infection, dizziness, and vomiting.

Orphan status: Yes

DRUG NAME	MANUFACTURER	APPROVAL DATE
IXCHIQ (CHIKUNGUNYA VACCINE, LIVE) SOLUTION FOR INTRAMUSCULAR INJECTION	TAKEDA PHARMACEUTICALS, INC.	11/09/2023

THERAPEUTIC CLASS
Vaccines

FDA-APPROVED INDICATION(S)
- Ixchiq™ is a vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are in high risk to exposure to CHIKV

DOSAGE AND ADMINISTRATION
- Administer Ixchiq™ as a single approximately 0.5 mL dose.
- For intramuscular use only

DOSAGE FORMS AND STRENGTHS
- Ixchiq™ is a solution for injection.
- After reconstitution, a single dose is approximately 0.5 mL.

SAFETY PROFILE

CONTRAINDICATIONS
- Immunocompromised individuals.
- Individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of Ixchiq™.

WARNINGS AND PRECAUTIONS
- Ixchiq™ may cause severe or prolonged chikungunya-like adverse reactions.
- Vertical transmission of wild-type CHIKV from pregnant individuals with viremia at delivery is common and can cause potentially fatal CHIKV disease in neonates. Vaccine viremia occurs in the first week following administration of Ixchiq™, with resolution of viremia by 14 days after vaccination. It is not known if the vaccine virus can be vertically transmitted and cause fetal or neonatal adverse reactions.
- Syncope (fainting) may occur in association with administration of injectable vaccines, including Ixchiq™. Procedures should be in place to avoid injury from fainting.

ADVERSE REACTIONS
- In clinical studies, the most common solicited injection site reaction (>10%) was tenderness (10.6%). The most common solicited systemic adverse reactions (>10%) were headache (31.6%), fatigue (28.5%), myalgia (23.9%), arthralgia (17.2%), fever (13.5%) and nausea (11.2%)

USE IN SPECIFIC POPULATION
- A decision to administer Ixchiq™ during pregnancy should take into consideration the individual's risk of wild-type CHIKV infection, gestational age, and risks to the fetus or neonate from vertical transmission of wild-type CHIKV

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
AUGTYRO™ (REPOTRECTINIB) CAPSULES FOR ORAL USE	BRISTOL-MYERS SQUIBB COMPANY	11/15/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).

DOSAGE AND ADMINISTRATION
- The recommended dosage is 160 mg orally once daily for 14 days, then increase to 160 mg twice daily, with or without food.
- Select patients for the treatment of locally advanced or metastatic NSCLC based on the presence of ROS1 rearrangement(s) in tumor specimens.
- Prior to initiating Augtyro™:
  - Discontinue strong and moderate CYP3A4 inhibitors for 3 to 5 elimination half-lives of the CYP3A4 inhibitor.
  - Evaluate liver function tests (including bilirubin) and uric acid level.

DOSAGE FORMS AND STRENGTHS
- Capsules: 40 mg

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- *Central Nervous System (CNS) Effects:* Can cause CNS adverse reactions including dizziness, ataxia, and cognitive impairment. Withhold and then resume at same or reduced dose upon improvement, or permanently discontinue Augtyro™ based on severity.
- *Interstitial Lung Disease (ILD)/Pneumonitis:* Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.
- *Hepatotoxicity:* Monitor liver function tests every 2 weeks during the first month of treatment, and as clinically indicated thereafter. Based on severity, withhold and then resume at same or reduced dose, or permanently discontinue.
- *Myalgia with Creatine Phosphokinase (CPK) Elevation:* Monitor serum CPK levels during treatment in patients reporting unexplained muscle pain, tenderness, or weakness. Based on severity, withhold and resume at same or reduced dose upon improvement.
- *Hyperuricemia:* Monitor serum uric acid levels prior to initiating and periodically during treatment. Initiate treatment with urate-lowering medications as clinically indicated. Withhold and resume at same or reduced dose, or permanently discontinue based on severity.
- *Skeletal Fractures:* Promptly evaluate patients with signs or symptoms (e.g., pain, changes in mobility, deformity) of fractures.
- *Embryo-Fetal Toxicity:* Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use an effective non-hormonal method of contraception.

ADVERSE REACTIONS
The most common adverse reactions (≥20%) were dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, ataxia, fatigue, cognitive disorders, and muscular weakness.

DRUG INTERACTIONS
- *Strong and Moderate CYP3A Inhibitors:* Avoid concomitant use.
- *P-gp inhibitors*: Avoid concomitant use.
- *Strong and Moderate CYP3A Inducers:* Avoid concomitant use. (7.1)
- *Certain CYP3A Substrates*: Avoid concomitant use with CYP3A substrates, where minimal concentration changes can cause reduced efficacy.
- *Hormonal contraceptives:* Avoid concomitant use.

DRUG NAME	MANUFACTURER	APPROVAL DATE
AUGTYRO™ (REPOTRECTINIB) CAPSULES, FOR ORAL USE	BRISTOL-MYERS SQUIBB COMPANY	11/15/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).

DOSAGE AND ADMINISTRATION
- The recommended dosage is 160 mg orally once daily for 14 days, then increase to 160 mg twice daily, with or without food.
- Select patients for the treatment of locally advanced or metastatic NSCLC based on the presence of ROS1 rearrangement(s) in tumor specimens.
- Prior to initiating Augtyro™:
  - Discontinue strong and moderate CYP3A4 inhibitors for 3 to 5 elimination half-lives of the CYP3A4 inhibitor.
  - Evaluate liver function tests (including bilirubin) and uric acid level.

DOSAGE FORMS AND STRENGTHS
- Capsules: 40 mg

Orphan status: Yes

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- *Pregnancy:* Based on its mechanism of action, Augtyro™ can cause fetal harm when administered to a pregnant woman.
- *Lactation*: Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed. during treatment and for 10 days after the last dose.
- *Females and Males of Reproductive Potential*: Verify the pregnancy status of females of reproductive potential prior to initiating treatment. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with Augtyro™ and for 2 months after the last dose. Advice males with female partners of childbearing potential to use effective contraception during treatment with Augtyro™ and for 4 months after the last dose.

DRUG NAME	MANUFACTURER	APPROVAL DATE
TRUQAP™ (CAPIVASERTIB) TABLETS, FOR ORAL USE	ASTRAZENECA PHARMACEUTICALS	11/16/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

DOSAGE AND ADMINISTRATION
- The recommended dosage is 400 mg orally twice daily, with or without food, for 4 days followed by 3 days off.
- Select patients for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer with Truqap™ based on the presence of one or more of the following genetic alterations in tumor tissue: PIK3CA/AKT1/PTEN.
- Evaluate fasting blood glucose (FG) and hemoglobin A1C (HbA1C) prior to starting TRUQAP and at regular intervals during treatment.

DOSAGE FORMS AND STRENGTHS
- Tablets: 160 mg and 200 mg

SAFETY PROFILE

CONTRAINDICATIONS
- Severe hypersensitivity to Truqap™ or any of its components.

WARNINGS AND PRECAUTIONS
- *Hyperglycemia:* Evaluate blood glucose levels prior to starting and at regular intervals during treatment. Withhold, reduce dose, or permanently discontinue Truqap™ based on severity
- *Diarrhea:* Truqap™ caused diarrhea in most patients. Advise patients to increase oral fluids, start antidiarrheal treatment, and consult with a healthcare provider if diarrhea occurs while taking Truqap™ . Withhold, reduce dose, or permanently discontinue Truqap™ based on severity.
- *Cutaneous Adverse Reactions:* Monitor for signs and symptoms of cutaneous adverse reactions. Withhold, reduce dose, or permanently discontinue Truqap™ based on severity.
- *Embryo-Fetal Toxicity*: Truqap™ can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥20%), including laboratory abnormalities, were diarrhea, cutaneous adverse reactions, increased random glucose, decreased lymphocytes, decreased hemoglobin, increased fasting glucose, nausea, fatigue, decreased leukocytes, increased triglycerides, decreased neutrophils, increased creatinine, vomiting and stomatitis

DRUG INTERACTIONS
- *Strong CYP3A Inhibitors*: Avoid concomitant use. If concomitant use cannot be avoided, reduce Truqap™ dose.
- *Moderate CYP3A Inhibitors*: Reduce Truqap™ dose.
- *Strong and Moderate CYP3A Inducers*: Avoid concomitant use.

USE IN SPECIFIC POPULATIONS
- *Pregnancy:* Based on its mechanism of action, Augtyro™ can cause fetal harm when administered to a pregnant woman.
- *Lactation*: Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed. during treatment.
- *Females and Males of Reproductive Potential*: Verify the pregnancy status of females of reproductive potential prior to initiating treatment. Advise females of reproductive potential to use effective contraception during treatment with Truqap™ and for 1 month after the last dose. Advice males with female partners of childbearing potential to use effective contraception during treatment with Truqap™ and for 4 months after the last dose.

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
RYZNEUTA™ (EFBEMALENOGRASTIM ALFA-VUXW) INJECTION, FOR SUBCUTANEOUS USE	EVIVE BIOTECHNOLOGY	11/16/2023

THERAPEUTIC CLASS
Colony Stimulating Factor

FDA-APPROVED INDICATION(S)
To decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

DOSAGE AND ADMINISTRATION
- The recommended dose is 20 mg administered subcutaneously once per chemotherapy cycle.
- Administer approximately 24 hours after cytotoxic chemotherapy. Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
- Ryzneuta™ is administered subcutaneously via a single-dose prefilled syringe by a healthcare professional.

DOSAGE FORMS AND STRENGTHS
- Injection: 20 mg/mL solution in a single-dose prefilled syringe

SAFETY PROFILE

CONTRAINDICATIONS
- Patients with a history of serious allergic reactions to granulocyte stimulating factors such as efbemalenograstim alfa-vuxw, pegfilgrastim, or filgrastim products.

WARNINGS AND PRECAUTIONS
- *Fatal splenic rupture*: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- *Acute respiratory distress syndrome (ARDS)*: Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue in patients with ARDS.
- *Serious allergic reactions, including anaphylaxis*: Permanently discontinue Ryzneuta™ in patients with serious allergic reactions.
- *Sickle cell crises in Patients with Sickle Cell Disorders:* Discontinue Ryzneuta™ if sickle cell crisis occurs.
- *Glomerulonephritis*: Evaluate and consider dose-reduction or interruption of Ryzneuta™ if causality is likely.
- *Thrombocytopenia:* Monitor platelet counts.
- *Capillary Leak Syndrome*: Monitor patients with symptoms; consider intensive care.
- *Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer*: Monitor patients with breast and lung cancer using Ryzneuta™ in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.

ADVERSE REACTION
- Most common adverse reactions (≥10%) were nausea, anemia, and thrombocytopenia.

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
OGSIVEO™ (NIROGACESTAT) TABLETS, FOR ORAL USE	SPRINGWORKS THERAPEUTICS INC	11/27/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
For adult patients with progressing desmoid tumors who require systemic treatment.

DOSAGE AND ADMINISTRATION
- The recommended dosage is 150 mg orally twice daily until disease progression or unacceptable toxicity.
- May be taken with or without food.
- Tablets must be swallowed whole.
- Permanently discontinue Ogsiveo™ for recurrence of severe or life-threatening adverse reaction upon rechallenge at the reduced dose.

DOSAGE FORMS AND STRENGTHS
- Tablets: 50 mg

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- *Diarrhea*: Severe diarrhea can occur. Monitor and dose modify for Grade 3-4 diarrhea.
- *Ovarian Toxicity*: Female reproductive function and fertility may be impaired. Advise females of reproductive potential of the potential risk prior to treatment and monitor routinely.
- *Hepatotoxicity:* Elevated AST and ALT can occur. Monitor AST and ALT regularly and modify dose as recommended.
- *Non-Melanoma Skin Cancers*: Perform dermatologic examination prior to initiation of Ogsiveo™ and routinely during treatment.
- *Electrolyte Abnormalities*: Monitor phosphate and potassium regularly and modify dose as recommended.
- *Embryo-Fetal Toxicity:* Can cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS
- The most common (> 15 %) adverse reactions are diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection and dyspnea.

ADVERSE REACTIONS-CONT.
- The most common laboratory abnormalities (≥15%) are decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

DRUG INTERACTIONS
- *Strong or moderate CYP3A inhibitors*: Avoid concomitant use.
- *Strong or moderate CYP3A inducers*: Avoid concomitant use.
- *Gastric acid reducing agents*: Avoid concomitant use with proton pump inhibitors and H2-receptor antagonists. If concomitant use cannot be avoided, Ogsiveo™ administration can be staggered with antacids.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on its mechanism of action, Ogsiveo™ can cause fetal harm when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed during treatment and for 1 week after the last dose.
- Females and Males of Reproductive Potential: Verify the pregnancy status of females of reproductive potential prior to initiating treatment. Advise females of reproductive potential and males with female partners of childbearing potential to use effective contraception during treatment with Ogsiveo™ and for 1 week after the last dose.

Orphan status: Yes

New Biosimilar Products

- No new biosimilar product approved in November.

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Voquezna (vonoprazan) tablets, for oral use / Phathom Pharmaceuticals, Inc.	11/01/2023	Ulcer Drugs/ antispasmodics	[1] For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. [2] To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. [3] In combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults [4] In combination with amoxicillin for the treatment of H. pylori in adults.	Voquezna™ is a first-in-class potassium- competitive acid blocker (P-CAB) that provides an alternative treatment option for patients with moderate to severe Erosive Esophagitis (EE), who do not response to lower –cost, generic, first line Proton Pump Inhibitor (PPI) therapy. Orphan: No
Zituvimet (sitagliptin and metformin hydrochloride) tablets, for oral use / Zydus Worldwide DMCC	11/03/2023	Antidiabetics	To improve glycemic control in type 2 diabetes patients	Zituvimet™ is a fixed –dose mixture of two ingredients sitagliptin and metformin. The treatment could enhance glycaemic control in type 2 diabetes mellitus patients. The approval provides an affordable treatment option for healthcare systems to reduce the rate of growth in drug spending and improves the financial sustainability of the healthcare programs. Orphan: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Zepbound (tirzepatide) injection, for subcutaneous use / Eli Lilly and Company	11/8/2023	Antiobesity agent	Treatment indicated adjunct to a reduce – calorie diet and increased physical activity for chronic weight management in adults with obesity and/or overweight in the presence of at least one weight – related comorbid condition.	Zepbound™ is the first and only dual GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic polypeptide) receptor agonist approved for chronic weight management. Orphan: No
Alvaiz™ (eltrombobag tablets), for oral use / Teva Pharms	11/29/2023	Hematopoietic Growth Factor	[1] For the treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids immunoglobulins, or splenectomy; [2] For the treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy; [3] For the treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.	Alvaiz™ shares the same indications as Promacta™. The safety and efficacy of Alvaiz™ have been established based on adequate and well-controlled studies of eltrombopag olamine in adult and pediatric patients 6 years and older with persistent or chronic ITP, adult patients with chronic hepatitis C-associated thrombocytopenia, and adult patients with refractory severe aplastic anemia. Orphan: No

New First-Time Generic Approvals

- No new first-time generics approved in November.

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Exparel™ (bupivacaine liposome) injectable suspension /	Non-opioid analgesics	[1] In patients 6 years of age and older for a single dose infiltration to produce postsurgical local anesthesia; [2] In adults as an interscalene brachial plexus nerve block to produce postsurgical regional anesthesia	Regional anesthesia: [1] A sciatic nerve block in the popliteal fossa in adults; [2] an adductor canal block in adults.	11/9/2023
Keytruda™ (pembrolizumab) injection / Merck Sharp Dohme	Antineoplastics	[1] Melanoma; [2] Non-small cell lung cancer (NSCLC); [3] Head and neck squamous cell cancer (HNSCC); [4] Classical Hodgkin lymphoma (cHL); [5] Primary mediastinal large B-cell lymphoma (PMBCL); [6] Urothelial carcinoma; [7] Microsatellite Instability–high or mismatch repair deficient cancer; [8] Gastric cancer; [9] Esophageal cancer; [10] Cervical cancer; [11] Hepatocellular carcinoma; [12] Merkel cell carcinoma; [13] Renal cell carcinoma; [14] Endometrial carcinoma; [15] Tumor mutational Burden-high cancer; [16] Cutaneous squamous cell carcinoma; [17] Triple-negative breast cancer	In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.	11/16/2023

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Xtandi™ (enzalutamide)	Antineoplastics	For the treatment of patients with [1] castration-resistant prostate cancer (CRPC); [2] metastatic castration-sensitive prostate cancer	Non-metastatic Castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)	11/16/2023

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
SPN- 830 (apomorphine) infusion device / Supernus Pharmaceuticals, Inc.	11/2/2023	Treatment for hypomobility in Parkinson's disease	SPN- 830 is a continuous subcutaneous infusion formulation of approved dopamine agonist apomorphine in development for the treatment for motor fluctuations (OFF episodes) in Parkinson's disease (PD). If is approved by the FDA it will be a novel and less invasive treatment option for PS patients. PDUFA goal date of April 5, 2024 NDA accepted	Moderate

References

- *New Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/newdrugs.html.
- *Latest Generic Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/generic-approvals.html.
- *New Indications & Dosage Forms for Existing Drugs*. Drugs.com. (2023). https://www.drugs.com/new-indications.html.
- *New Drug Applications*. Drugs.com. (2023). https://www.drugs.com/new-drug-applications.html.
- *Drugs@FDA: FDA-Approved Drugs. Accessdata.FDA.gov. (2023). https://www.accessdata.fda.gov/scripts/cder/daf/.*