Are you offering your patients with diabetes a cost-effective insulin option?

You can if you stock Lilly’s Insulin Lispro Injection U-100. It’s the same molecule as Humalog® U-100, but at a lower list price that may be more affordable for some of your customers.*

*For many commercially insured patients, Humalog may still be less expensive than Insulin Lispro Injection.

- Same safety profile and clinical efficacy
- Same manufacturer and molecule
- Same KwikPen® and vial

Even if an HCP writes Humalog U-100 you can dispense either product. For order or stocking information, visit lillytrade.com†

†State laws vary.

For customers who need help paying for their Lilly insulin prescription, encourage them to call Lilly Diabetes Solution Center at 1-833-808-1234, Monday through Friday, 9 AM to 8 PM ET.

Indication for Humalog and Insulin Lispro Injection

- Humalog and Insulin Lispro Injection are rapid-acting human insulin analogs indicated to improve glycemic control in adults and children with diabetes mellitus.

Select Important Safety Information

Contraindications

- Humalog and Insulin Lispro Injection are contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of its excipients.

Please see Important Safety Information for Humalog U-100 and Insulin Lispro Injection U-100 on the next page and Brief Summary of Prescribing Information on the following pages.
Important Safety Information for Humalog and Insulin Lispro Injection

Contraindications
• Humalog and Insulin Lispro Injection are contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of its excipients.

Warnings and Precautions
• Never Share a Humalog or an Insulin Lispro Injection KwikPen® or Syringe Between Patients: Humalog and Insulin Lispro Injection KwikPen must never be shared between patients, even if the needle is changed. Patients using a Humalog or Insulin Lispro Injection vial must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.
• Changes in Insulin Regimen: Changes may affect glycemic control and predispose to hypoglycemia or hyperglycemia. These changes should be made cautiously under close medical supervision and the frequency of blood glucose monitoring should be increased.
• Hypoglycemia: Severe hypoglycemia may be life threatening and can cause seizures or death. Hypoglycemia is the most common adverse reaction of Humalog or Insulin Lispro Injection. The patient’s ability to concentrate and react may be impaired as a result of hypoglycemia. Hypoglycemia can happen suddenly and symptoms may vary for each person and may change over time. Early warning symptoms of hypoglycemia may be different or less pronounced under conditions such as long-standing diabetes, diabetic nerve disease, use of medications such as beta-blockers, or in patients who experience recurrent hypoglycemia. These situations may result in severe hypoglycemia and possibly loss of consciousness prior to the patient’s awareness of hypoglycemia. Timing of hypoglycemia usually reflects the time-action profile of administered insulins which may vary in different individuals or at different times in the same individual. Other factors such as changes in food intake, injection site, exercise, and concomitant medications may increase the risk of hypoglycemia. Educate patients to recognize and manage hypoglycemia. In patients at higher risk for hypoglycemia and patients with reduced symptomatic awareness, increased frequency of blood glucose monitoring is recommended. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia.
• Hypersensitivity Reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with Humalog or Insulin Lispro Injection. If hypersensitivity reactions occur, discontinue Humalog or Insulin Lispro Injection and treat per standard of care until signs and symptoms resolve.
• Hypokalemia: Hypokalemia may be life threatening. Insulins, including Humalog and insulin lispro injection, cause a shift in potassium from the extracellular to intracellular space possibly leading to hypokalemia, which, if untreated, may result in respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia (eg, patients using potassium-lowering medications or medications sensitive to serum potassium concentrations).

Warnings and Precautions, continued
• Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists: Thiazolidinediones (TZDs), which are PPAR-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin, including Humalog and Insulin Lispro Injection. This may lead to or exacerbate heart failure. Observe patients for signs and symptoms of heart failure and consider discontinuation or dose reduction of the PPAR-gamma agonist.
• Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction: Malfunction of the insulin pump device, infusion set, or insulin degradation can rapidly lead to hyperglycemia and ketoacidosis. Patients using subcutaneous insulin infusion pumps must be trained to administer insulin by injection and have alternate insulin therapy available in case of pump failure.

Drug Interactions
• Some medications may alter glucose metabolism, insulin requirements, and the risk for hypoglycemia or hyperglycemia. Signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs. Particularly close monitoring may be required.

Adverse Reactions
• Adverse reactions associated with Humalog and Insulin Lispro Injection include hypoglycemia, hypokalemia, allergic reactions, injection-site reactions, lipodystrophy, pruritus, rash, weight gain, and peripheral edema.

Use in Specific Populations
• Humalog and Insulin Lispro Injection have not been studied in children with type 1 diabetes less than 3 years of age or in children with type 2 diabetes.

Dosage and Administration
• Humalog and Insulin Lispro Injection should be given within 15 minutes before or immediately after a meal.
• Humalog or Insulin Lispro Injection can be administered intravenously under medical supervision with close monitoring of blood glucose and potassium levels to avoid hypoglycemia and hypokalemia.
• Humalog or Insulin Lispro Injection for subcutaneous injection should only be mixed with NPH insulin. If Humalog or Insulin Lispro Injection is mixed with NPH insulin, Humalog or Insulin Lispro Injection should be drawn into the syringe first. Injection should occur immediately after mixing. Humalog or Insulin Lispro Injection should not be diluted or mixed when used in an external insulin pump. Change Humalog or Insulin Lispro Injection in the reservoir at least every 7 days. Change the infusion set and insertion site at least every 3 days.

Please see Humalog and Insulin Lispro Injection Brief Summary of Prescribing Information on the following pages. Please see Instructions for Use included with Humalog and Insulin Lispro Injection products.
WARNINGS AND PRECAUTIONS

**Never share prefilled pens, needles, cartridges, reusable pens compatible with Lilly 3 ML cartridges, or syringes between patients:**
even if the needle is changed. Patients using vials must never share needles or syringes with another person.

**Hypoglycemia:**
Hypoglycemia is the most common adverse reaction of Humalog and Insulin Lispro Injection. Severe hypoglycemia may be life-threatening and can cause seizures or death. The patient’s ability to concentrate and react may be impaired as a result of hypoglycemia. Hypoglycemia can happen suddenly. Symptoms may vary for each person and change over time. Early warning symptoms of hypoglycemia may be different or less pronounced in patients with long-standing diabetes or diabetic nerve disease or in patients who use medications such as beta-blockers or experience recurrent hypoglycemia. These situations may result in severe hypoglycemia and possible loss of consciousness prior to the patient’s awareness of hypoglycemia.

Timing of hypoglycemia usually reflects the time-action profile of administered insulins which may vary in different individuals or at different times in the same individual. Other factors such as changes in food intake, injection site, exercise, and concomitant medications may increase the risk of hypoglycemia.

Educate patients to recognize and manage hypoglycemia. Self-monitoring of blood glucose is essential for patients receiving insulin therapy. Increase monitoring frequency with changes to insulin dosage, use of glucose-lowering medications, meal pattern, and physical activity. In patients with reduced symptomatic awareness or that have a higher risk for hypoglycemia, such as those with renal or hepatic impairment, increased frequency of blood glucose monitoring is recommended.

**Hypoglycemia Due to Medication Errors:**
Accidental mix-ups between insulin products can occur. Instruct patients to always check the insulin label before each injection to avoid medication errors. Do not transfer Humalog U-200 from the KwikPen to a syringe as overdosage and severe hypoglycemia can occur.

**Hypersensitivity Reactions:**
Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with Humalog and Insulin Lispro Injection. If hypersensitivity reactions occur, discontinue Humalog or Insulin Lispro Injection and treat per standard of care until signs and symptoms resolve.

**Hypokalemia:**
May be life threatening. All insulin products including Humalog and Insulin Lispro Injection cause a shift in potassium from the extracellular to intracellular space possibly leading to hypokalemia. Untreated hypokalemia may result in respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.

**Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists:**
Thiazolidinediones (TZDs), which are PPAR-gamma agonists, can cause dose-related fluid retention when used in combination with insulin, including Humalog and Insulin Lispro Injection. This may lead to or exacerbate heart failure. Observe patients for signs and symptoms of heart failure. If heart failure develops, treat per standard of care and consider discontinuation or dose reduction of the PPAR-gamma agonist.

**Hypoglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction:**
Malfunction of the insulin pump device, infusion set, or infusion of insulin for continuous subcutaneous infusion can rapidly lead to hyperglycemia and ketoacidosis. Patients using Humalog U-100 or Insulin Lispro Injection U-100 in subcutaneous insulin infusion pumps must be trained to administer insulin by injection and have alternate insulin therapy available in case of pump failure.

**OVERDOSE:**

- **Humalog or Insulin Lispro Injection:**
  - Do not use Humalog or Insulin Lispro Injection:
    - During episodes of hypoglycemia.
    - In patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of the excipients in Humalog or Insulin Lispro Injection.

- **Humalog U-200 from the KwikPen to a syringe as overdosage and severe hypoglycemia can occur.

- **Humalog or Insulin Lispro Injection:**
  - Do NOT perform dose conversion when using any Humalog or Insulin Lispro Injection.
  - Continuous subcutaneous infusion (insulin pump): Humalog U-100 or Insulin Lispro Injection.
  - Do not mix Humalog U-100 or Insulin Lispro Injection U-100 with any other insulin for continuous subcutaneous infusion. Do not mix Humalog U-200 with any other insulin.

**CONTRAINDICATIONS**

- Do not use Humalog or Insulin Lispro Injection:
  - During episodes of hypoglycemia.
  - In patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of the excipients in Humalog or Insulin Lispro Injection.

**Adverse Reactions**

Adverse reactions associated with Humalog and Insulin Lispro Injection include hypoglycemia, hypokalemia, allergic reactions, injection-site reactions, lipodystrophy, pruritus, rash, weight gain, and peripheral edema.

- **Insulin Initiation and Intensification of Glucose Control:**
  - Rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.

- **Lipodystrophy:**
  - Long-term use of insulin, including Humalog and Insulin Lispro Injection, can cause lipodystrophy at the site of repeated insulin injections or infusion. Lipodystrophy includes lipoatrophy (thinning of adipose tissue) and lipoatrophy (thinning of adipose tissue) and may affect insulin absorption. Rotate insulin injection or infusion sites within the same region to reduce the risk of lipodystrophy.

- **Weight Gain:**
  - Weight gain can occur with insulin therapy, including Humalog and Insulin Lispro Injection, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

- **Peripheral Edema:**
  - Insulin, including Humalog and Insulin Lispro Injection, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

- **Allergic Reactions:**

  - **Local Allergy**—As with any insulin therapy, patients taking Humalog or Insulin Lispro Injection may experience redness, swelling, or itching at the site of the injection. These minor reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of Humalog or Insulin Lispro Injection. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

  - **Systemic Allergy**—Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with any insulin, including Humalog and Insulin Lispro Injection. Generalized allergy to insulin may cause whole body rash (including pruritus), dyspnea, wheezing, hypotension, tachycardia, or diaphoresis.

In controlled clinical trials, pruritus (with or without rash) was seen in 17 patients receiving regular human insulin (n=2969) and 30 patients receiving Humalog or Insulin Lispro Injection (n=2944). Localized reactions and generalized myalgias have been reported with injected metacresol, which is an excipient in Humalog and Insulin Lispro Injection.
Do not use Humalog or Insulin Lispro Injection:

**CONTRAINDICATIONS**

Humalog and Insulin Lispro Injection are rapid-acting insulin analogs indicated to improve glycemic control in adults and children with diabetes mellitus.

**INDICATIONS AND USAGE**

- Do NOT perform dose conversion when using any Humalog or Insulin Lispro Injection.
- Intravenous Infusion: Administer Humalog U-100 or Insulin Lispro Injection.
- Continuous subcutaneous infusion (insulin pump): Humalog U-100 or Insulin Lispro Injection KwikPens.
- Subcutaneous Injection: Humalog or Insulin Lispro Injection should be used with any other insulin.

**DOSING**

Individualize and adjust the dosage of Humalog or Insulin Lispro Injection by injection and have alternate insulin therapy available in case of pump failure.

**USE IN SPECIFIC POPULATIONS**

- **Pregnancy—** Published studies with the use of insulin lispro during pregnancy have not reported an association between insulin lispro products and major birth defects, miscarriage, or adverse maternal or fetal outcomes. However, these studies cannot definitively establish or exclude the absence of any risk because of methodological limitations in the study design. Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia-related morbidity.

- **Lactation—** There are no data on the presence of Humalog or Insulin Lispro Injection in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for insulin, any potential adverse effects on the breastfed child from Humalog or Insulin Lispro Injection, or from the underlying maternal condition.

- **Pediatric Use—** Humalog and Insulin Lispro Injection are approved for use in children for subcutaneous daily injections. Only the U-100 formulations of Humalog and Insulin Lispro Injection are approved for use in children by continuous subcutaneous infusion in insulin pumps. Humalog and Insulin Lispro Injection have not been studied in pediatric patients younger than 3 years of age or in pediatric patients with type 2 diabetes.

- **Renal or Hepatic Impairment—** Patients with renal or hepatic impairment may be at increased risk of hypoglycemia and may require more frequent Humalog or Insulin Lispro Injection dose adjustment and more frequent blood glucose monitoring.

**OVERDOSE**

Excess insulin administration may cause hypoglycemia and hypokalemia. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

**PATIENT COUNSELING INFORMATION**

See FDA-approved patient labeling and Patient Counseling Information section of the Full Prescribing Information.

**See Brief Summary of Prescribing Information on adjacent page.** See Instructions for Use accompanying the pen or vial. Additional information can be found at https://www.humalog.com/hcp/, https://www.lillyinsulinlispro.com, or The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).
Looking Back at 2019, and Planning Ahead

Change is constant. We know that the pace is only accelerating in health care. The editors of Drug Topics recognize the myriad challenges you face in improving the lives of your patients, navigating a complicated and increasingly competitive business ecosystem, and using and implementing technologies to advance the quality of care for your patients.

As we get ready to close out 2019, the Drug Topics team would like to thank you for engaging with our digital and print content, for responding to our surveys, and for sharing your ideas with your colleagues to solve real business, economic, and career challenges throughout the year. As the leading source of information for pharmacists, our pledge is to help simplify complex issues and offer useful and actionable insights in print, online, through video and other multimedia, and in social media.

In short, we want to help you expand your business skills and rediscover the joy of working in pharmacy.

In 2020, we know there will be a renewed focus on collaborating across health care specialties while reducing costs. To meet the challenge, we are building content targeting the most pressing business issues facing pharmacists.

In every issue of Drug Topics, you will gain the advice you need to further your career—regardless of where you work. You will explore content devoted to technology, diabetes care, respiratory conditions, autoimmune disorder treatments, vaccine updates, and pain control. You will hear from your colleagues on a variety of key topics and receive up-to-the-minute news coverage on drug approvals, key policy updates, and of course, our very popular pharmacy conference coverage.

Thank you again for your time and support.

Look for us online at drugtopics.com and in print, and please don’t hesitate to connect so that we can help improve healthcare together.

Mike Hennessy, Sr.,
Chairman and Founder of MJH Life Sciences
EDITORIAL MISSION: Drug Topics is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
Salaries & Stress STAGNATE

Satisfaction lies deeper

By Nicholas Hamm, managing editor

Every year, Drug Topics’ asks pharmacists about their job experiences. In particular, we’re interested in what pharmacists are interested in: what’s the payment like for a pharmacist’s expertise, and how stressful is the job overall?

As in previous years, we found that pharmacists are well paid, but also stressed out. So what’s stressing you out? The over 1,100 pharmacists Drug Topics’ surveyed cited everything from vaccination quotas to DIR fees to new USP regulations as their biggest concerns. While fewer pharmacists said that their stress levels increased at work this year compared to 2018, the number was still high: 61.08%.

As far as salary goes, pharmacists are largely making close to what they made last year (see Base Annual Salary). Looking at the beginning of the decade, however, the 2010 survey showed that the average salary was lower, with the majority (62.5%) reporting salaries in the $100,000-130,000 range. In 2019, nearly 40% made that amount, while nearly 50% said they make over that $130,000 mark.

High stress levels aside, pharmacists are still, overall, fairly satisfied with their jobs. More than twice as many (18%) said they were “extremely satisfied” with their job compared to those who said they were “extremely dissatisfied” (9%) and the majority said they were either “very satisfied” or “satisfied.” On top of this, just 22% of pharmacists were looking for a new position in the next 12 months.

EXCLUSIVE SALARY SURVEY RESULTS

Page 12
NOW APPROVED
Reblozyl®
(luspatercept-aamt)
for injection 25mg • 75mg

THE FIRST AND ONLY ERYTHROID MATURATION AGENT (EMA)
for anemia in adults with β-thalassemia requiring regular red blood cell transfusions

REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

Thromboembolic events (TEE) were reported in 8/223 (3.6%) REBLOZYL-treated patients. TEEs included deep vein thrombosis, pulmonary embolus, portal vein thrombosis, and ischemic stroke. Patients with known risk factors for thromboembolism (splenectomy or concomitant use of hormone replacement therapy) may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients at increased risk of TEE. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly.

Hypertension

Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients. Across clinical studies, the incidence of Grade 3 to 4 hypertension ranged from 1.8% to 8.6%. In patients with beta thalassemia with normal baseline blood pressure, 13 (6.2%) patients developed systolic blood pressure (SBP) >130 mm Hg and 33 (16.6%) patients developed diastolic blood pressure (DBP) >80 mm Hg. Monitor blood pressure prior to each administration. Manage new or exacerbations of preexisting hypertension using anti-hypertensive agents.

Embryo-Fetal Toxicity

REBLOZYL may cause fetal harm when administered to a pregnant woman. REBLOZYL caused increased post-implantation loss, decreased litter size, and an increased incidence of skeletal variations in pregnant rat and rabbit studies. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurring in 1% of patients included cerebrovascular accident and deep vein thrombosis. A fatal adverse reaction occurred in 1 patient treated with REBLOZYL who died due to an unconfirmed case of acute myeloid leukemia (AML).

Most common adverse reactions (at least 10% for REBLOZYL and 1% more than placebo) were headache (26% vs 24%), bone pain (20% vs 8%), arthralgia (19% vs 12%), fatigue (14% vs 13%), cough (14% vs 11%), abdominal pain (14% vs 12%), diarrhea (12% vs 10%) and dizziness (11% vs 5%).

LACTATION

It is not known whether REBLOZYL is excreted into human milk or absorbed systemically after ingestion by a nursing infant. REBLOZYL was detected in milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because many drugs are excreted in human milk, and because of the unknown effects of REBLOZYL in infants, a decision should be made whether to discontinue nursing or to discontinue treatment. Because of the potential for serious adverse reactions in the breastfed child, breastfeeding is not recommended during treatment and for 3 months after the last dose.

Please see the Brief Summary of full Prescribing Information for REBLOZYL on the following pages.


Learn more, sign up for updates, and find out how to access REBLOZYL at: REBLOZYLpro.com/findoutmore

REBLOZYL® is a registered trademark of Celgene Corporation.
REBLOZYL® is licensed from Acceleron Pharma Inc.
**REBLOZYL®** (luspatercept-aamt) for injection, for subcutaneous use

The following is a Brief Summary; refer to full Prescribing Information for complete product information.

1 **INDICATIONS AND USAGE**

1.1 Beta Thalassemia

REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

**Limitations of Use**

REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 **DOSAGE AND ADMINISTRATION**

2.1 Recommended Starting Dosage in Beta Thalassemia

The recommended starting dose of REBLOZYL is 1 mg/kg once every 3 weeks by subcutaneous injection.

If a planned administration of REBLOZYL is delayed or missed, administer REBLOZYL as soon as possible and continue dosing as prescribed, with at least 3 weeks between doses. Assess and review hemoglobin (Hgb) results prior to each administration. If an RBC transfusion occurred prior to dosing, the pretransfusion Hgb must be considered for dosing purposes.

If the pre-dose Hgb is greater than or equal to 11.5 g/dL and the Hgb level is not influenced by recent transfusion, delay dosing until the Hgb is less than or equal to 11 g/dL.

2.2 Dose Increases during Treatment

**Beta Thalassemia**

If a patient does not achieve a reduction in RBC transfusion burden after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose, increase the REBLOZYL dose to 1.25 mg/kg.

Do not increase the dose beyond the maximum dose of 1.25 mg/kg.

2.3 Continuation and Discontinuation Recommendations

If a patient experienced a response followed by a lack of or lost response to REBLOZYL, initiate a search for causative factors (e.g., a bleeding event). If typical causes for a lack or loss of hematologic response are excluded, follow dosing recommendations for management of patients with an insufficient response to REBLOZYL therapy [see Dosage and Administration (2.2)].

Discontinue REBLOZYL if a patient does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose level or if unacceptable toxicity occurs at any time [see Dosage and Administration (2.2)].

2.4 Preparation and Administration

REBLOZYL should be reconstituted and administered by a healthcare professional.

Reconstitute REBLOZYL with Sterile Water for Injection, USP only.

<table>
<thead>
<tr>
<th>Vial Size</th>
<th>Amount of Sterile Water for Injection, USP required for reconstitution</th>
<th>Final Concentration</th>
<th>Deliverable Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg vial</td>
<td>0.68 mL</td>
<td>25 mg/0.5 mL</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>75 mg vial</td>
<td>1.6 mL</td>
<td>75 mg/1.5 mL (50 mg/mL)</td>
<td>1.5 mL</td>
</tr>
</tbody>
</table>

Reconstitute the number of REBLOZYL vials to achieve the appropriate dose based on the patient's weight. Use a syringe with suitable graduations for reconstitution to ensure accurate dosage.

**Reconstitution Instructions**

1. Reconstitute with Sterile Water for Injection, USP using volumes described in Table 1 (Reconstitution volumes) with the stream directed onto the lyophilized powder. Allow to stand for one minute.
2. Discard the needle and syringe used for reconstitution. The needle and syringe used for reconstitution should not be used for subcutaneous injections.
3. Gently swirl the vial in a circular motion for 30 seconds. Stop swirling and let the vial sit in an upright position for 30 seconds.
4. Inspect the vial for undissolved particles in the solution. If undissolved powder is observed, repeat step 3 until the powder is completely dissolved.
5. Invert the vial and gently swirl in an inverted position for 30 seconds. Bring the vial back to the upright position, and let it sit for 30 seconds.
6. Repeat step 5 seven more times to ensure complete reconstitution of material on the sides of the vial.

7. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. REBLOZYL is a colorless to slightly yellow, clear to slightly opalescent solution which is free of foreign particulate matter. Do not use if undissolved product or foreign particulate matter are observed.

8. If the reconstituted solution is not used immediately:

- Store at room temperature at 20°C to 25°C (68°F to 77°F) in the original vial for up to 8 hours. Discard if not used within 8 hours of reconstitution.
- Alternatively, store refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours in the original vial. Remove from refrigerated condition 15-30 minutes prior to injection to allow solution to reach room temperature for a more comfortable injection. Discard if not used within 24 hours of reconstitution.
- Do not freeze the reconstituted solution.

Discard any unused portion. Do not pool unused portions from the vials. Do not administer more than 1 dose from a vial. Do not mix with other medications.

**Instructions for Subcutaneous Administration**

Calculate the exact total dosing volume of 50 mg/mL solution required for the patient. Slowly withdraw the dosing volume of the reconstituted REBLOZYL solution from the single-dose vial(s) into a syringe. Divide doses requiring larger reconstituted volumes (i.e., greater than 1.2 mL) into separate similar volume injections and inject into separate sites. If multiple injections are required, use a new syringe and needle for each subcutaneous injection.

Administer the injection subcutaneously into the upper arm, thigh, and/or abdomen.

4 **CONTRAINDICATIONS**

None.

5 **WARNINGS AND PRECAUTIONS**

5.1 Thrombosis/Thromboembolism

In adult patients with beta thalassemia, thromboembolic events (TEE) were reported in 8/223 (3.6%) REBLOZYL-treated patients. Reported TEEs included deep vein thromboses, pulmonary embolism, portal vein thrombosis, and ischemic strokes. Patients with known risk factors for thromboembolism, e.g. splenectomy or concomitant use of hormone replacement therapy, may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients with beta thalassemia at increased risk of TEE. Monitor patients receiving REBLOZYL for signs and symptoms of thromboembolic events and institute treatment promptly.

5.2 Hypertension

Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients. Across clinical studies, the incidence of grade 3-4 hypertension ranged from 1.8% to 8.6%. In adult patients with beta thalassemia with normal baseline blood pressure, 13 (6.2%) patients developed systolic blood pressure (SBP) > 130 mm Hg and 33 (16.6%) patients developed diastolic blood pressure (DBP) > 80 mm Hg. Monitor blood pressure prior to each administration. Manage new-onset hypertension or exacerbations of preexisting hypertension using anti-hypertensive agents.

5.3 Embryo-Fetal Toxicity

Based on findings from animal reproductive studies, REBLOZYL may cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of luspatercept-aamt to pregnant rats and rabbits during organogenesis resulted in adverse developmental outcomes including increased embryo-fetal mortality, alterations to growth, and structural abnormalities at exposures (based on area under the curve [AUC]) above those occurring at the maximum recommended human dose (MRHD) of 1.25 mg/kg.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective method of contraception during treatment with REBLOZYL and for at least 3 months after the final dose [see Use in Specific Populations (8.1, 8.3)].

6 **ADVERSE REACTIONS**

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Thrombosis/Thromboembolism [see Warnings and Precautions (5.1)]
- Hypertension [see Warnings and Precautions (5.2)]
## 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data in the WARNINGS AND PRECAUTIONS reflect exposure to REBLOZYL as a single agent administered across a range of doses (0.125 mg/kg to 1.75 mg/kg) in 571 patients in 4 trials. Beta Thalassemia

The safety of REBLOZYL in patients with beta thalassemia was evaluated in the BELIEVE trial [see Clinical Studies (14.1)]. Key eligibility criteria included adult patients with beta thalassemia (with exception of S/β-thalassemia) without major organ damage or recent DVT stroke and platelet counts less than or equal to 1000 × 10^9/L.

Patients received a starting dose of REBLOZYL 1 mg/kg subcutaneous injection every 3 weeks. Overall, 53% of patients had their dose increased to 1.25 mg/kg (46% REBLOZYL, n = 223) or placebo (54%, n = 109). The median duration of treatment was similar between the REBLOZYL and placebo arms (63.3 weeks vs. 62.1 weeks, respectively). Per protocol, patients in the REBLOZYL and placebo arms were to remain on therapy for at least 48 weeks in the double-blind phase of the trial.

Among patients receiving REBLOZYL, 94% were exposed for 6 months or longer and 72% were exposed for greater than one year.

The median age of patients who received REBLOZYL was 30 years (range: 18, 96); 59% female; 54% White and 36% Asian.

### Serious adverse reactions occurred in 3.6% of patients on REBLOZYL

### Serious adverse reactions reported in 1% of patients were cerebrovascular accident and deep vein thrombosis. A fatal adverse reaction occurred in one patient treated with REBLOZYL who died due to an unconfirmed case of AML (M6).

Permanent discontinuation due to an adverse reaction (Grades 1-4) occurred in 5.4% of patients who received REBLOZYL. Most frequent adverse reactions requiring permanent discontinuation in patients who received REBLOZYL included arthralgia (1%), back pain (1%), bone pain (<1%), and headache (<1%).

Dosage reductions due to an adverse reaction occurred in 2.7% of patients who received REBLOZYL. Most frequent adverse reactions requiring dosage reduction in >0.5% of patients who received REBLOZYL included hypertension and headache.

Dosage interruptions due to an adverse reaction occurred in 15.2% of patients who received REBLOZYL. Most frequent adverse reactions requiring dosage interruption in >1% of patients who received REBLOZYL included upper respiratory tract infection, ALT increase, and cough.

The most common adverse reactions (at least 10% for REBLOZYL and 1% more than placebo) were headache (26%), bone pain (20%), arthralgia (19%), fatigue (14%), cough (14%), abdominal pain (14%), diarrhea (12%), and dizziness (11%).

Table 2 summarizes the adverse reactions in BELIEVE.

### Table 2: Adverse Drug Reactions (>5%) in Patients Receiving REBLOZYL with a Difference Between Arms of 1% in BELIEVE Trial

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>REBLOZYL (N=223)</th>
<th>Placebo (N=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades n (%)</td>
<td>Grades ≥3 n (%)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Pain</td>
<td>44 (20)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>43 (19)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Infections and infestation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td>19 (9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Viral Upper Respiratory Infection</td>
<td>14 (6)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>58 (26)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>25 (11)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>30 (14)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

(continued)

### Gastrointestinal disorders

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>REBLOZYL (N=223)</th>
<th>Placebo (N=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades n (%)</td>
<td>Grades ≥3 n (%)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal Pain b</td>
<td>31 (14)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>27 (12)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>20 (9)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

b Grouped term includes: abdominal pain and abdominal pain upper.

### Vascular disorders

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>REBLOZYL (N=223)</th>
<th>Placebo (N=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades n (%)</td>
<td>Grades ≥3 n (%)</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension c</td>
<td>18 (8)</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>

**b Grouped term includes: essential hypertension, hypotension, and hypertensive crisis.**

### Metabolism and nutrition disorders

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>REBLOZYL (N=223)</th>
<th>Placebo (N=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades n (%)</td>
<td>Grades ≥3 n (%)</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>16 (7)</td>
<td>6 (3)</td>
</tr>
</tbody>
</table>

### Respiratory, thoracic and mediastinal disorders

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>REBLOZYL (N=223)</th>
<th>Placebo (N=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades n (%)</td>
<td>Grades ≥3 n (%)</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>32 (14)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
REBLOZYL® (luspatercept-aamt) for injection, for subcutaneous use

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

In embryo-fetal development studies, luspatercept-aamt was administered subcutaneously at 5, 15, or 30 mg/kg on gestation days 3 and 10 (rats) or 5, 20, or 40 mg/kg on gestation days 4 and 11 (rabbits). Effects in both species included reductions in numbers of live fetuses and fetal body weights, and increases in resorptions, post-implantation losses, and skeletal variations (such as asymmetric sternal centra in rats and angulated hyoid in rabbits). Effects were observed at exposures (based on AUC) approximately 13-times (rats) and 18-times (rabbits) the MRHD of 1.25 mg/kg.

In a pre- and postnatal development study, pregnant rats were administered luspatercept-aamt subcutaneously at 3, 10, or 30 mg/kg once every 2 weeks during organogenesis and through weaning, gestation day 6 through postnatal day 20. At all dose levels lower F1 pup body weights and adverse kidney findings (such as membranoproliferative glomerulonephritis, tubular atrophy/hypoplasia, and vessel ectasia occasionally associated with hemorrhage) were observed. These effects were observed at exposures (based on AUC) approximately 1.6-times the MRHD of 1.25 mg/kg.

8.2 Lactation

Luspatercept-aamt was detected in milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. There are no data on the presence of REBLOZYL in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed child, advise females not to breastfeed during treatment with REBLOZYL and for 3 months after the last dose.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential before starting REBLOZYL treatment.

Contraception

Females

REBLOZYL may cause embryo-fetal harm when administered to pregnant women [see Use in Specific Populations (8.1)]. Advise female patients of reproductive potential to use effective contraception during treatment with REBLOZYL and for at least 3 months after the last dose.

Infertility

Females

Based on findings in animals, REBLOZYL may impair female fertility [see Nonclinical Toxicology (13.1)]. Adverse effects on fertility in female rats were reversible after a 14-week recovery period.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Based on findings in juvenile animals, REBLOZYL is not recommended for use in pediatric patients [see Non-Clinical Toxicology (13.1)].

8.5 Geriatric Use

Clinical studies of REBLOZYL in beta thalassemia did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently from younger subjects.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or mutagenicity studies have been conducted with luspatercept-aamt.

In a repeat-dose toxicity study, juvenile rats were administered luspatercept-aamt subcutaneously at 1, 3, or 10 mg/kg once every 2 weeks from postnatal day 7 to 91. Hematologic malignancies (granulocytic leukemia, lymphocytic leukemia, malignant lymphoma) were observed at 10 mg/kg resulting in exposures (based on area under the curve [AUC]) approximately 8 times the maximum recommended human dose (MRHD) of 1.25 mg/kg.

In a combined male and female fertility and early embryonic development study in rats, luspatercept-aamt was administered subcutaneously to animals at doses of 1 to 15 mg/kg. There were significant reductions in the average numbers of corpora lutea, implantations, and viable embryos in luspatercept-aamt-treated females. Effects on female fertility were observed at the highest dose with exposures (based on AUC) approximately 7 times the MRHD of 1.25 mg/kg. Adverse effects on fertility in female rats were reversible after a 14-week recovery period. No adverse effects were noted in male rats.

17 PATIENT COUNSELING INFORMATION

Discuss the following with patients prior to and during treatment with REBLOZYL.

Thromboembolic Events

Advise beta thalassemia patients of the potential risk of thromboembolic events. Review known risk factors for developing thromboembolic events and advise patients to reduce modifiable risk factors (e.g., smoking, use of oral contraceptives) [see Warnings and Precautions (5.1)].

Effects on Blood Pressure

Caution patients that REBLOZYL may cause an increase in blood pressure [see Warnings and Precautions (5.2)].

Embryo-Fetal Toxicity

Advise females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception while receiving REBLOZYL and for at least 3 months after the final dose. Advise females to contact their healthcare provider if they become pregnant, or if pregnancy is suspected, during treatment with REBLOZYL [see Warnings and Precautions (5.3) and Use in Specific Populations (8.2)].

Lactation

Advise females not to breastfeed during treatment with REBLOZYL and for 3 months after the final dose [see Use in Specific Populations (8.2)].

Manufactured by:

Celgene Corporation
86 Morris Avenue
Summit, NJ 07901
U.S. License No. 2114

Jointly Marketed by:

Acceleron Pharma, Inc.
Cambridge, MA 02139

REBLOZYL® is a registered trademark of Celgene Corporation.

Patent: www.celgene.com/therapies

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Please rate your satisfaction with your current position:

<table>
<thead>
<tr>
<th>Extremely Dissatisfied</th>
<th>Somewhat Dissatisfied</th>
<th>Satisfied</th>
<th>Very Satisfied</th>
<th>Extremely Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>19%</td>
<td>30%</td>
<td>24%</td>
<td>18%</td>
</tr>
</tbody>
</table>

Within the past year, has your stress level at work:

- Decreased: 2019 - 4%, 2018 - 5%
- Remained the same: 2019 - 29%, 2018 - 31%
- Increased: 2019 - 66%, 2018 - 61%

Within the past year, has your workload:

- Decreased: 2016 - 4%, 2017 - 4%, 2018 - 4%, 2019 - 4%
- Remained the same: 2016 - 22%, 2017 - 29%, 2018 - 23%, 2019 - 24%
- Increased: 2016 - 72%, 2017 - 66%, 2018 - 72%, 2019 - 69%

Why has your stress level at work increased:

- Increased work volume: 81%
- Inadequate staff support: 69%
- Increase pressure from management: 56%
- Increased paperwork: 45%
- Negative workplace environment: 33%
- Lack of training and continuing education: 16%

Other: 16%
Q: Did you receive any additional income in 2019? (commission, bonus, profit-sharing, etc.)

Yes: 36%
No: 64%

Q: On average, how much additional income did you receive in 2019?

Base annual salary

<table>
<thead>
<tr>
<th>Range</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>$70,000 or less</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>$70,001-$80,000</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>$80,001-$90,000</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>$90,001-$100,000</td>
<td>4%</td>
<td>4%</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>$100,001-$110,000</td>
<td>11%</td>
<td>7%</td>
<td>7%</td>
<td>9%</td>
</tr>
<tr>
<td>$110,001-$120,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$120,001-$130,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$130,001-$140,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$140,001-$150,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over $150,000</td>
<td></td>
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</tr>
</tbody>
</table>
Technology has long pushed the limits of the possible in pharmacy. From the days of the best available lenses to help identify the seeds, flowers, and leaves that once provided the basic ingredients for most pharmaceuticals, to the latest in wearable electronics, technology has been a key driver in the effort to improve patient outcomes. All are changing the ways patients, pharmacists, and other providers work together to improve health.

The Uber Model in Pharmacy
Instead of looking at pharmacy as physical stores or centralized call centers, Aspen RxHealth sees pharmacists as a community of providers serving patients who need their specialized knowledge and skills.

“Apexn’s software connects community pharmacists with clinical practice services, health plans, or patients who have signed up for the service,” explains Carmen Catizone, MS, RPh, DP, executive director of the National Association of Boards of Pharmacy.

Humana is using Aspen to provide services for Medicare Advantage patients in the Tampa, FL area with plans to expand the program later in 2019. Aspen’s panel of community pharmacists will provide medication therapy management, patient education, and answer general questions about drug therapy.

Wearables
Wearable pharmacy technology is a reality and it’s not just limited to consumer-oriented products like the FitBit or Apple Watch. For example, Amgen’s Neulasta (pegfilgrastim) is available in a wearable autoinjector for patients receiving chemotherapy.

The adhesive on-body injector is usually placed on the arm or abdomen immediately after the final chemotherapy infusion. The automated injector lets the patient rest at home instead of traveling back to a provider for one more injection and ensures that patients actually get the colony-stimulating factor to stimulate neutrophil production and reduce the risk of infection following chemotherapy.

Custom Packaging Boosts Profits
The same repackaging machines that spit out strips of single tablets can be adapted to package multiple tablets to be taken at the same time in a single bubble.

For patients, packaging multiple medications together is added convenience; for pharmacies, it’s added profit.

“Why stop at packaging Rx meds that can be taken together?” asks Cliff Holt, PharmD, president of Hurricane Family Pharmacy in Gunnison and Hurricane, UT. “You can make things even more convenient for your patients by adding their regular OTCs and supplements to the same bubble as their prescription meds.

Continuous Glucose Monitoring
Regular fingerpricks, test strips, and glucometers to measure blood glucose levels are moving into history. Continuous glucose monitors (CGMs) let patients track glucose levels 24/7, upload data to their cell phones, and automatically send it to providers.

Direct involvement in outcomes makes a clear case for service-based reimbursement above and beyond device and medication reimbursement.

Pharmacist eCare Plan
The Pharmacist eCare Plan (PeCP) is an interoperable standard that allows for a common method to exchange information related to patient care delivery.

“PeCP lets pharmacists document clinical services and patient activities that they have been doing for years,” says Lisa Schwartz, PharmD, senior director for professional affairs at NCPA.

PeCP marks the first time pharmacy care data can be exchanged directly with other providers using an HL7 (Health Level Seven International Electronic Health Record) transaction.

“This communication standard lets pharmacists move beyond our siloed care team into the broader medical world,” Schwartz says.
Why Choose Greenstone Authorized Generics?

• **Legacy:**
  Greenstone has been providing authorized generic versions of Pfizer products for over 25 years

• **Quality:**
  Greenstone authorized generics are always backed by Pfizer quality standards

• **Product Consistency:**
  Greenstone Authorized Generics are the same as the brand-name drug but do not use the brand name on the label and may have a different color or marking.

Excerpt from FDA statement regarding Authorized Generics:

“An authorized generic drug is the same as the brand-name drug but does not use the brand name on the label. In addition, an authorized generic version of a tablet or capsule may have a different color or marking. Because an authorized generic drug is marketed under the brand name drug’s New Drug Application (NDA), it is not listed in FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book). An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug.”

1 FDA.gov - Search: FDA List of Authorized Generic Drugs (updated 12/27/2018)
Top Pharmacy Stories of 2019

By Karen Berger, PharmD

As 2019 draws to a close, let’s look back at some of the top pharmacy news stories of the year. In no particular order:

**Insulin Coverage**

The increasing price of insulin has been widely reported in 2019. Patients are traveling to Canada in search of cheaper insulin; many report rationing insulin to make it “last longer.” Insulin prices have tripled in the last decade; manufacturers are under pressure to lower prices.

Novo Nordisk, Sanofi, and Eli Lilly are the three biggest suppliers of insulin worldwide. All three companies have announced plans to attempt to lower costs in the near future, through authorized generics, manufacturer coupons, and discounted prices.

As the price of insulin has skyrocketed, insurance companies are getting involved. In April, Cigna and its PBM, Express Scripts, announced a new program for patients with diabetes in the commercial plan that would limit the copay of a 30-day supply of insulin to $25.

**Closings, Layoffs**

After cutting bonuses and making 2018 benefit changes, Walgreens said Q1 2019 was “difficult” and the company stated that it would save another $500 million per year (in December 2018, the company pledged to save $1 billion per year). Walgreens also said it would close 750 of the acquired Rite Aid stores, 150 more stores than first reported.

CVS also announced a slowing of expansion and plans to close 22 more stores next year. Fred’s Pharmacy announced that all remaining stores would be closing and the company filed for bankruptcy.

**USP General Chapter <800>**

USP (US Pharmacopeia) General Chapter <800> went into effect on December 1.

Formally titled USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, it provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment.

**Opioid Crisis and Lawsuits**

In the “Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids” released in September by the Office of the Inspector General, findings stated “that DEA does not capture sufficient data to detect the diversion of opioids or emerging drug trends in a timely manner.” The report states that despite the alarmingly increasing rates of deaths due to opioids, the DEA was allowing manufacturers to produce larger quantities of opioids, and that the DEA was “slow to respond to the significant increase in the use and diversion of opioids since 2000.”

The Sackler family, founders of Purdue Pharma, is being sued in thousands of cases. The family amassed a $13 billion fortune mostly from sales of OxyContin; they are accused of pushing OxyContin sales by deceiving prescribers and patients, even though they allegedly knew how dangerous and addictive the drug was. Purdue Pharma filed for bankruptcy in September.

Johnson & Johnson recently agreed to settle an Ohio opioid lawsuit for $20.4 million, and in August paid a $572 million settlement for its involvement in the Oklahoma opioid crisis. Several other companies are also facing lawsuits.

**CBD Popularity Grows**

In 2019, CBD exploded in popularity. Cannabis research firm Brightfield Group projects CBD sales to exceed $5 billion by the end of 2019, a 706% increase from last year. The company projects that the CBD industry’s total market value could reach $23.7 billion by 2023.
Osteoarthritis is the most common type of arthritis, affecting nearly 54 million people. The condition causes a great deal of pain and distress, as well as limitations in daily activities and mobility, says Marcy O’Koon, senior director of Consumer Health at the Arthritis Foundation.

While opioids might seem to be an obvious solution, O’Koon says opioids are now discouraged—not just because of the nation’s opioid crisis and tightening access, but because there is a new recognition that they don’t work all that well. “Staying physically active and losing weight, if needed, are at the top of the list,” O’Koon says.

O’Koon recommends taking a 5- to 10-minute walk throughout the week and incrementally increasing the time and/or pace. Endurance will increase and the pain may recede over time.

It’s also helpful to look at risks in groups. O’Koon points to CDC population surveys that have found that 50% of adults with heart disease and 50% of adults with diabetes have arthritis.

“Those groups have double reason to be physically active. If they are overweight and sedentary too, then overall health suffers.”

Pharmacists can help older adults who have osteoarthritis as well as heart disease. A major concern is that many of these individuals may be taking a lot of over-the-counter NSAIDs without their doctors’ knowledge.

A new study recently published in Arthritis Care & Research suggests there is a great need for improvement for managing older patients with arthritis. The study examined 2,297 physician visits for knee osteoarthritis and found rates for visits to orthopedists and physical therapists declined from 2007 to 2015. At the same time, prescriptions for NSAIDs and narcotics or opioids increased.

Lead author Samannaaz Khoja, PT, PhD, research assistant professor at the University of Pittsburgh School of Health and Rehabilitation Sciences’ Department of Physical Therapy says physicians tend to be more focused on helping patients manage their pain with medications, without considering the long-term benefits of exercise for mitigating declines in physical health.

“Pain control should be just one aspect of treatment. The focus is mainly on pain medications; there should be greater emphasis on nonpharmacological approaches,” Khoja says.

Tom Bateman, PharmD, clinical assistant professor Ernest Mario School of Pharmacy Rutgers, The State University of New Jersey, New Brunswick, says because acetaminophen has a favorable safety profile when compared to alternatives like NSAIDs or opioid analgesics, it is considered the gold standard for treatment of osteoarthritis. The general principle of “start low, go slow” when dosing should be applied when recommending acetaminophen, says Bateman.

“If patients require additional pain control or if high doses of acetaminophen are not appropriate due to reduced hepatic function or alcohol use, then multimodal pain strategies can be used,” Bateman says. “Some would consider cannabis as a newer therapy. “

The Arthritis Foundation recently released the first CBD guidance for adults with arthritis. While there are no established clinical guidelines for CBD use, medical experts who worked in partnership with the Arthritis Foundation agree that CBD may help with arthritis-related symptoms; however, this has not been confirmed in clinical studies.
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Offering immunizations is a smart business move, especially for independent pharmacies. According to the 2018 NCPA Digest, 73% of community pharmacies now offer immunization services, although only a quarter of these pharmacies offer more than flu shots.

“Immunizations have actually become an issue of competitive parity,” says John Beckner, RPh, senior director of strategic initiatives at NCPA. “You can’t go to work for a chain these days without being certified to do immunizations. They make it mandatory for their pharmacists to do them. If you’re an independent pharmacist and you’re not doing them, you are really at a competitive disadvantage.”

State Laws for Pharmacist Immunization

Pharmacists are able to give flu vaccinations in all 50 states as well as Washington, DC and Puerto Rico, but a patchwork of state regulations govern which other vaccines can be administered, which protocol must be followed, and the minimum age patients must be before they can be immunized at a pharmacy.

A promising source of revenue for both chain and independent pharmacies is the inclusion of travel clinics that offer necessary CDC-recommended travel vaccinations, such as yellow fever, cholera, and malaria. States often put more restrictions around travel vaccines, such as needing a physician-signed protocol or prescription to administer.

“Practice acts are unlikely to look the same from one state to another,” says Jeffrey Goad, PharmD, MPH, professor and chair, department of pharmacy practice, Chapman University School of Pharmacy. “Within one state’s pharmacy practice act, that state can have very detailed regulations that describe which vaccines, which ages, and under which circumstances a vaccine may be given by a pharmacist.”

While some state details can cover pages, other states may have regulations that consist of a single sentence, authorizing a pharmacist to independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), according to CDC guidelines, and on patients older than three years.

“The US does not really have an oversight body or process for creating regulations specific to pharmacists in each state,” says Lauren Angelo, PharmD, MBA, assistant dean of academic affairs and associate professor of pharmacy practice at Rosalind Franklin University of Medicine and Science. “In some states, there are no restrictions on the types of vaccines or age limits.”

Given the absence of an oversight body or process, the trend to expand pharmacists’ authority is being enacted slowly, on a state-by-state basis.

The latest update to state regulations was enacted in October in North Carolina. The new regulations lowered both the minimum age for flu shots in pharmacies and added the authority to administer adult immunizations including: herpes zoster, hepatitis A and B, meningococcal, HPV, and tetanus. In 2018, Missouri lowered the minimum age requirement for immunizations from 12 to 7 years, if authorized by a physician; Iowa authorized vaccination, pursuant to...
Vaccines / State Laws and Vaccination Services

From a convenience standpoint, it’s much easier to just drop in to your pharmacy than to make a doctor’s appointment.

JOHN BECKNER, NCPA

...to statewide protocols, to any patient over the age of six months. Pennsylvania currently has a bill in committee that, if passed, would also lower the minimum age.

Authority to immunize has also been expanded during disease outbreaks, as was the case during the 2018 flu season when Governor Andrew M. Cuomo signed an executive order to let New York’s pharmacists administer flu vaccines to children from ages 2 to 18. The order was given in response to the rising number of reported cases—previously, pharmacists could only administer the flu vaccine to patients 18 and older.

“Laws and regulations are getting more friendly toward pharmacists immunizing,” says Beckner. “The restrictions tend to be either with age or certain vaccines and I think things are moving in the direction of pharmacists being able to give all the adult vaccines that the ACIP recommends. We have a way to go as certain states are more restrictive than others, but we’re definitely moving in that direction.”

States may grant authority to immunize independently, through a collaborative agreement or via a prescription. As of 2016, 17 states let pharmacists independently administer select vaccines, while the other 33 states, Puerto Rico, and Washington, DC followed other protocols.

“Collaborative practice agreements often take time and financial resources on the part of the pharmacist and physician to maintain,” says Goad. “States that require a prescription for certain vaccines definitely drive up the cost by requiring a patient to see the physician just to get a prescription for a vaccine that they then have to go to the pharmacy and have administered. The pharmacist still has to screen the patient for appropriateness even though there is a prescription.”

Looking to the Future

According to Mitchel C. Rothholz, RPh, MBA, chief strategy officer for the American Pharmacists Association (APhA), the APhA vision for pharmacy-based immunizations is that pharmacists in every state should ultimately have the ability to administer any ACIP recommended vaccines. That goal is being realized on a state-by-state basis.

“Getting there is working with individual states, working closely in partnership with the National Alliance of State Pharmacy Associations (NASPA), and the state associations, trying to address this on a state level, working through what their priorities and needs are,” says Rothholz.

Achieving the vision could benefit both pharmacists and patients. A study by the Pacific Research Institute suggests that letting pharmacists administer all adult vaccinations recommended by the CDC could help raise the vaccination rate and save lives. Statistics suggest that if immunizations are offered at convenient hours for patients (ie, at night, on weekends, and without having to make a doctor’s appointment), more people will get immunized.

That’s an important consideration—90,000 Americans die of vaccine-preventable deaths annually in the United States.

Obstacles and Opportunities

In the last 3 years, Idaho (2017), Rhode Island (2018), and Utah (2019) passed bills that allow technicians to immunize patients, freeing up pharmacists to focus on other services.

“When pharmacy technicians can immunize, under the supervision of the pharmacist, it frees the pharmacist to engage in other patient care or counseling type activities,” says Beckner. “The role of the technician is expanding. They’re able to do more and more and they’re certainly able to do the technical tasks. That frees the pharmacist to do the cognitive functions and tasks that require judgment in the pharmacy.”

More states now also require pharmacists to report immunizations to registries, since digital records can help coordinate care among patients and multiple health professionals. All 50 states, US territories, and the District of Columbia have at least one regional or local immunization registry.

“People can access those registries and we can find out if somebody has gotten, say, dose two of the two-dose series,” says Beckner. “If they forget whether they got their pneumonia vaccine, the pharmacy can access the registry and find out without having to rely on the patient to provide that information.”

Another obstacle standing in the way of more vaccinations in pharmacies is training. While most graduates of pharmacy school have received immunization training, state laws don’t necessarily require it.

“Not all states specify training or even when they do, how much training or by what method,” says Goad. “That’s why state laws are antiquated as pharmacists follow the standard of practice which is the national training program or a program that mimics the CDC immunization training program. In addition, the school of pharmacy accrediting body stipulates that immunization training must occur. So, even with state law, the science and practice of pharmacy-based immunization has moved ahead. State laws are just out of date and can present an obstacle to people getting the vaccines they need, putting patient lives at risk.”
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As the opioid crisis rages on (130 people die of opioid overdoses each day), pharmacists face a number of challenges: how do you keep potentially dangerous medications from those who abuse them while not making things overly difficult for the chronic pain patients who rely on them—all while maintaining a busy pharmacy?

While counseling is important, it’s difficult to do when there’s a massive backlog of unfilled orders. To help manage that, pharmacists at the recent NCPA convention in San Diego gave a talk titled “Caring for Patients on Opioids.”

In the talk, Lorri Gebo-Shaver, PharmD, owner of Shaver Pharmacy & Compounding Center in Pocatello, ID; Caitie Brown, PharmD, PGY-I resident at Pharmacy & Compounding Center; and Shanna O’Connor, PharmD, assistant professor, College of Pharmacy at Idaho State University gave tips on how her pharmacy manages to help patients in the real world.

The first real step, O’Connor said, is to ask good questions. She said that it goes against what’s often done the pharmacy: the pharmacy is busy and pharmacists are overwhelmed, so they stick to largely yes/no questions to help speed along the process. She said in this case, however, it is important to ask open-ended questions that can help reveal a patient’s true situation.

In Idaho, pharmacists are able to prescribe naloxone, which Gebo-Shaver does for certain patients and has them sign a form acknowledging that she offered it to them—this creates a paper trail that helps protect her and her pharmacy, as well as shows the seriousness of the situation to the patient.

Even so, she said that “having that conversation at first is really hard.” One of those hard questions involves naloxone—as Gebo-Shaver said, “How do you say appropriately what naloxone is for?” She said she compares it to epinephrine, saying that it’s something that can save your life in an accident—perhaps even for someone you don’t know.

She described one patient who, when offered naloxone, initially declined. But that patient then returned to her pharmacy the next day with his wife and son who he wanted to attend the training as well. He said that he had a friend recently pass away from an overdose, and was so thankful that the pharmacy was willing to take time to provide education.

To begin the workflow (Fig. 1), start by looking at pain holistically through a pain inventory. This can help the pharmacist make an informed decision about alternatives. As O’Connor said, “What got us into this situation is that we got very comfortable with very high doses of opioids,” so providing alternatives to those high doses is key.

The important thing to remember,
Gebo-Shaver, stressed, is that the pharmacist isn’t the only one able to help. While technician duties vary by state, in Idaho where they are given more abilities, Gebo-Shaver says she sees herself as a quarterback in her pharmacy who is protected and helped out by a defensive line. (For states with weaker technician powers, she advocates reaching out to state boards of pharmacy and advocating for enhanced abilities).

O’Connor pointed to a workflow used to intake a new patient using an opioid monitoring form. With this form (Fig. 2), as well as checking the state’s PDMP, O’Connor says most of the information can be collected before the patient’s packet gets to the pharmacist. This process also provides paperwork that can protect the pharmacist and create a record showing that patients were given correct counseling.

So, the speakers said, ask yourself questions such as “what steps does your state require be completed by the pharmacist, and what could be done by a technician or cashier?”

Utilizing a process that protects both patients and pharmacists doesn’t have to be time consuming—while it does take time, the speakers stressed that the more a pharmacist does it, the faster it goes. ■

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**Figure 2** Opioid Monitoring Form

**Purpose:** to ensure patient access to safe and effective pain management therapy by improving patient education and interdisciplinary coordination through implementation of the CDC Guidelines for Prescribing Opioids for Chronic Pain.

**Name:** __________________ M or F (Circle one) **Date of Birth:** __________ Date: __________

**Phone:** __________ **Address:** __________

**Allergies:** [If known, please indicate reaction and date of occurrence]

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1. Is this for short term (<14 days), long-term (>14 days), or hospice therapy?
   - Hospice
   - Acute
   - Chronic

2. Have you tried other therapies for your pain?
   - Yes
   - No

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3. Do you use alcohol?
   - Yes
   - No

4. Do you use tobacco?
   - Yes
   - No

5. Do you have a history of sleep apnea, emphysema, asthma, or COPD?
   - Yes
   - No

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6. Have you used opioids (hydrocodone, oxycodone, Norco, Lortab, etc.) in the past?
   - Yes
   - No

7. Do you use benzodiazepines (lorazepam, diazepam, alprazolam, Ativan, Xanax, etc.)?
   - Yes
   - No

8. Have you used medications for other than their prescribed purposes?
   - Yes
   - No

9. Have you ever used illegal drugs or been diagnosed with a substance use disorder?
   - Yes
   - No

---

Next three questions are for long-term pain management therapy only, skip if <14 days of therapy.

10. What number best describes your pain on average in the past week:
    - (no pain) 0 1 2 3 4 5 6 7 8 9 10 (worst imaginable pain)

11. What number, for the past week, best describes how pain has interfered with your enjoyment of life:
    - (no pain) 0 1 2 3 4 5 6 7 8 9 10 (complete interference)

12. What number, for the past week, best describes how pain has interfered with your general activity:
    - (no pain) 0 1 2 3 4 5 6 7 8 9 10 (complete interference)

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**For Pharmacy Staff Only**

1. If hospice, patient is exempt from all monitoring and follow-up. If acute therapy, arrange follow-up phone call in 3 days. If chronic therapy, arrange follow-up phone call at 2 weeks.

2. Assess if opioid is appropriate. Educate on non-opioid options for pain control.

3. If yes: emphasize interaction with opioids and offer naloxone. If no: still provide counseling point.

4. If yes: consider closer follow-up with patients and offer naloxone, evidence suggests smokers at higher risk of overdose.

5. If yes: patient is at high risk of potentially significant respiratory depression, counsel patient and offer naloxone.

6. If yes: ask about previous indication and how they worked for the patient. If no: continue.

7. If yes: call provider and make aware of interaction and offer naloxone. If no: continue.

8. If yes: higher risk of misuse, offer naloxone. If no: continue.

9. If yes: offer naloxone and provide close follow-up and monitoring. If no: continue.

10. 10-12: Skip if acute therapy. In Chronic Therapy, will allow pharmacists to assess efficacy for long-term therapy.

Calculate MME using table in Protocol or Excel Document:

- Be sure to include both long-acting and short-acting formulations
- If sig provides a range, use most frequent dosing per sig

**MME Calculated:**

**Assessment/Action taken:**

Upload sheet into Strand and document encounter.

**Pharmacist Signature:** __________ **Date:** __________
Pharmacists can play an integral role in transitions-of-care for patients with chronic obstructive pulmonary disease (COPD) to prevent hospital readmissions. COPD affects at least 16 million individuals in the U.S., according to the CDC. This disease causes airflow blockage and breathing-related problems, which can affect daily activities and ultimately lead to hospitalization and death. Hospital and community pharmacists can play an important role in transitions-of-care for patients with COPD through medication management and education.

COPD Transitions-of-Care in Health Systems
Melissa Santibañez, PharmD, assistant professor, Department of Clinical and Administrative Sciences at Larkin University College of Pharmacy, Miami, FL says most patients presenting with COPD exacerbations will be admitted to the intensive care unit (ICU) because they develop acute hypercapnic respiratory failure (high carbon dioxide levels) requiring emergent endotracheal intubation and mechanical ventilation for respiratory support.

All COPD patients—regardless of their staging along the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria—should be on maintenance long-acting bronchodilator inhaler therapy, using either a long-acting muscarinic antagonist (LAMA) or long-acting beta-agonist (LABA), and also on short-acting bronchodilator rescue inhaler therapy, using a short-acting beta-agonist (SABA) if and when needed.

Use of an inhaled corticosteroid at different intensities of dosing is also possible as an adjunct to LAMA/LABA maintenance with SABA rescue. Evidence suggests that LAMAs may have a greater effect on reducing exacerbation rates than LABA treatment. Systemic corticosteroids are recommended for acute COPD exacerbations, with guidelines supporting prednisone 40-50 mg orally once daily for five days.

“I believe that the most consistent contribution that a critical care clinical pharmacist can make to ensure optimal care for the COPD exacerbation patient after transition from the ICU comes from medication reconciliation,” says Santibañez.

She adds that the pharmacist’s role in reviewing the patient’s verified home medication list against the list of inpatient therapies initiated during the exacerbation period and recommending changes to the chronic COPD management plan.

“I especially caution patients and caregivers against continuing systemic corticosteroid therapy after the exacerbation (unless if indicated for another reason), and I verify that they know what their chronic and rescue medications are at the current moment,” says Santibañez. Critical care pharmacists can facilitate the final discharge medication counseling by handing off any pertinent medication-related concerns post-exacerbation to their pharmacist colleagues on the corresponding floor/ward service or on the transition of care side.

“My number one clinical pearl that I emphasize is that inhalers for COPD are daily medications just like pills for hypertension,” says Paul Boylan, PharmD, BCPS, assistant professor, Department of Clinical and Administrative Sciences, Larkin University College of Pharmacy, Miami, FL.

Boylan says that if patients need to use rescue inhalers two or more times per week, then it may be a sign that their COPD is uncontrolled and they need to see a provider. “During my postgraduate training, my mentors emphasized the importance of ‘discharge begins on admission,’” says Boylan.

His goal is to see his COPD patients every day while they are admitted so they can establish a rapport before discharge. Boylan and his students make post-discharge appointments for patients with...
their primary care providers or specialists. They also follow-up with a 15- to 20-minute telehealth phone call to assess patients’ symptoms and see if they picked up their prescriptions from the community pharmacy. Boylan adds that it is important to update the home medication list in the electronic medical record to ensure it reflects all of the current treatments in case the patient is readmitted to the hospital.

**Community Pharmacists and COPD Transitions-of-Care**

It is important for community pharmacists to ensure that COPD patients are up-to-date on their immunizations, especially the influenza and pneumococcal vaccines to prevent serious illness (e.g., lower respiratory tract infections) and death.

Counseling on smoking cessation that includes the 5 As (Ask, Advise, Assess, Assist, and Arrange), should be incorporated into patient education. When patients pick up their prescriptions, pharmacists should assess their inhaler technique.

According to a study published in Federal Practitioner, a COPD care service consisting of a clinical pharmacist and nurse improved access to follow-up care and patient education at the time of transition from hospital to home. The study identified patients recently hospitalized for COPD, and clinic follow-up was coordinated by a clinical pharmacist and nurse within 30 days of hospital or emergency room discharge. Disease monitoring as well as patient-self monitoring of COPD was improved through this interprofessional approach to patient care. Pharmacists can play an integral role in the community setting by collaborating with the entire healthcare team to ensure that COPD patients are appropriately managed when transitioning from the hospital to the community setting.

Ahzam Afzal, PharmD is founder and managing partner at Frontizo, located in Bingham Farms, MI. Frontizo is a chronic care management company that services patients in 18 different states and is covered for all Medicare and Medicare advantage plans as well as through most commercial and private payers. The program services patients nationally across physician practices, hospitals, accountable care organizations, and independent physician associations and has reduced COPD exacerbations by following-up with each patient monthly to determine whether there are any signs/symptoms of exacerbations.

“Our patients are connected to our remote patient monitoring sensors, which helps provide us with an objective view of the patient’s condition at various points each day,” says Afzal. Frontizo provides continuous and episodic monitoring of the patient through their propriety technology platforms and 24/7 nursing team, which allows them to identify any readings that deviate from patient-specific, physician-set parameters. When a reading falls outside of the normal parameters, the nursing team reaches out in real-time and connects with the patient almost instantly to coach and triage appropriately.

Medication Therapy Management (MTM) is provided by Frontizo’s team of pharmacists who connect with the patient’s pharmacies, third-party payers, and providers to identify issues relating to medication adherence, safety, access, and therapy/dose effectiveness to ensure these gaps are identified and addressed immediately.

“In our experience with COPD, we particularly notice gaps in adherence due to medication access as a result of high cost prescriptions, lack of transportation, as well as a lack of fundamental understanding of therapy. By providing social worker and pharmacist-directed services as an integral segue through our MTM program, we are able to ensure that the barriers to adherence are addressed efficiently and in real-time,” says Afzal.

### COPD Maintenance Medications

**Beta2-Agonists**

**Short-acting (SABA)**
- Medications: Fenoterol, levalbuterol, albuterol, terbutaline

**Long-acting (LABA)**
- Medications: Formoterol, formoterol, indacaterol, olodaterol, salmeterol

Counseling points: May cause increased heart rate, tremors, and insomnia (take 1-2 hours before bedtime); may consider switching to different beta2-agonist if side effects are difficult to tolerate

**Anticholinergics**

**Short-acting (SAMA)**
- Medications: Ipratropium bromide, oxitropium bromide

**Long-acting (LAMA)**
- Medications: Tiotropium bromide, glycopyrronium bromide, tiotropium, umeclidinium, glycopyrrolate, robenacine

Counseling points: Dry mouth is a common side effect

**Combination product in one device (SABA/SAMA)**
- Medications: Fluticasone/salmeterol, formoterol/salmeterol, ipratropium/salbutamol

Counseling points: Combination may be more effective than each medication alone

**Combination product in one device (LABA/LAMA)**
- Medications: Formoterol/umeclidinium, formoterol/indacaterol/umeclidinium, vilanterol/umeclidinium, olodaterol/tiotropium

Counseling points: Combination may improve lung function

**Methylxantines**
- Medications: Aminophylline, theophylline

Counseling points: Side effects include nausea, vomiting, heart palpitations, and seizures

**Combination product in one device (LABA/inhaled steroid)**
- Medications: Formoterol/beclometasone, formoterol/budesonide, formoterol/mometasone, salmeterol/fluticasone, vilanterol/fluticasone furoate

Counseling points: Inhaled steroids may cause sore throat and mouth infections, so it’s important to rinse mouth and gargle after using inhaler

**Phosphodiesterase-4 Inhibitor Roflumilast**
- Counseling points: Side effects may include diarrhea, nausea, decreased appetite, abdominal pain, sleep problems, and headache

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**Medications:**
- **Inhaled Steroids:**
  - Medications: Fluticasone, budesonide, mometasone, beclomethasone, ciclesonide, dexamethasone, and triamcinolone

- **Combination Medications:**
  - Medications: Fmoterol/salmeterol, vilanterol/ fluticasone, tiotropium/olodaterol, and umeclidinium/vilanterol

**Counseling Points:**
- Side effects include dry mouth, increased heart rate, tremors, insomnia, and tremors
- May cause increased heart rate, tremors, and insomnia (take 1-2 hours before bedtime)
- May consider switching to different beta2-agonist if side effects are difficult to tolerate

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**Side Effects:**
- Side effects of beta2-agonists include increased heart rate, tremors, and insomnia
- Side effects of anticholinergics include dry mouth
- **Methylxantines:**
  - May cause nausea, vomiting, heart palpitations, and seizures

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**Respiratory / COPD**

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**Side Effects:**
- Diarrhea, nausea, decreased appetite, abdominal pain, sleep problems, and headache
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