The FDA approved 35 new drugs in 2011. Of these we will specifically discuss eight that seem like they will have the biggest immediate impact on therapy. We’ll present 5 in this lesson. The other 3 were discussed in the previous lesson.

This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings. The program ID # for this lesson is 707-000-12-005-H01-P. Pharmacists completing this lesson by May 31, 2015 may receive full credit.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the new drugs approved during 2011.
2. Discuss the role of these new drugs in therapy.
3. Summarize the new drugs’ adverse effects & potential drug interactions.
4. Recommend counseling points associated with the new drugs.

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.
INTRODUCTION

The Food and Drug Administration (FDA) approved 35 new chemical entities in 2011 compared to only 21 in the previous year.¹ In the past decade; only one other year saw such a high number of approvals. That was 2009 when there were 37 approvals. A number of clinical breakthrough agents were approved this past year, including 2 for hepatitis C, the first new agent for lupus in 50 years and 7 agents that are major advancements in cancer treatment. Almost 50% of these agents were given “priority” review, which accelerates the safety and efficacy review process to 6 months. A total of 10 agents were approved for rare or “orphan” diseases.

OUR DISCUSSIONS CONCENTRATE ON 8 OF THESE NEW DRUGS. THREE WERE PRESENTED IN THE PREVIOUS LESSON—TICAGRELOR, LINAGLIPTIN & RIVAROXABAN.

IN THIS LESSON WE CONCENTRATE ON 5 MORE NEW DRUGS. THEY ARE:

1 & 2. Telaprevir (Incivek™) & Boceprevir (Victrelis™)—both are G.I. drugs (oral protease inhibitors); used for chronic hepatitis C.

3. Fidaxomicin (Dificid™)—an infectious disease/immunology drug (macrolide antibiotic); used for Clostridium difficile-associated diarrhea.

4. Roflumilast (Daliresp™)—a respiratory/pulmonary agent (oral phosphodiesterase type 4 inhibitor); used to reduce COPD exacerbations.

5. Indacaterol (Arcapta™)—a respiratory/pulmonary agent (long-acting beta-agonist); used to treat COPD.

TELAPREVI R (INCIVEK™) AND BOCEPREVI R (VICTRELIS™)

Hepatitis C infection is transmitted primarily through large or repeated exposure to infectious blood.¹¹ These exposures can occur through injection drug use, needle stick injuries, perinatal transmission, and receipt of infected blood, blood products, or organs. The virus is infrequently transmitted through sexual intercourse or the sharing of personal items contaminated with HCV-infected blood (i.e. toothbrushes, razors). The signs and symptoms of acute HCV infection are usually mild if symptoms occur at all. Initial symptoms include fever, fatigue, jaundice, abdominal pain, nausea, and vomiting. The majority of patients chronically infected with HCV are asymptomatic; however, the disease may become severe leading to eventual cirrhosis and liver cancer. Overall, an estimated 3.2 million Americans are infected with chronic HCV and 8,000 to 10,000 deaths are attributed to chronic HCV infection in the US annually.

In 2011, the FDA approved 2 new agents for the treatment of Hepatitis C, telaprevir and boceprevir.¹²,¹³ When one of these agents is combined with standard therapy of peginterferon alfa and ribavirin, the sustained virological response (SVR) rate increases from 50% to 75%.

Pharmacology/Pharmacokinetics

Telaprevir and boceprevir are directly acting antiviral agents.¹²,¹³ They inhibit HCV NS3/4A protease and prevent viral replication. Both agents have short half-lives requiring three times a day dosing. Telaprevir must be taken with at least 20 grams of fat in order to achieve adequate absorption; boceprevir should be taken with food, but does not require the additional fat intake. Both agents are metabolized by the liver and excreted primarily in the feces.

Indications

Both agents are approved for treatment of chronic hepatitis C genotype 1 infection in combination with peginterferon alfa and ribavirin in adults with compensated liver disease.¹²,¹³

Dosing

Telaprevir

Administer 750 mg (two 375 mg tablets) 3 times daily with food for 12 weeks (given with peginterferon alfa and ribavirin).¹⁴,¹² Patients will continue peginterferon alfa and ribavirin for an additional 12 or 36 weeks based on viral
response. Telaprevir should be taken with a meal or snack that contains at least 20 grams of fat. Doses must be at least 7 to 9 hours apart.

**Boceprevir**

Treatment with boceprevir begins after 4 weeks of peginterferon alfa and ribavirin. Administer 800 mg (four 200 mg capsules) 3 times daily with food for 24 to 36 weeks.

**Contraindications**

Coadministration of potent CYP3A4/5 inducers or drugs highly dependent on CYP3A4/5 for clearance are contraindicated with both telaprevir and boceprevir. They are also contraindicated in pregnant women or in men whose female partners are pregnant.

Since these agents are administered with peginterferon alfa and ribavirin, contraindications to peginterferon and ribavirin should be considered when initiating therapy.

**Drug Interactions**

Table 1. Major drug interactions involving telaprevir and boceprevir.

<table>
<thead>
<tr>
<th>Interacting Medications</th>
<th>Interaction Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protease inhibitors</strong></td>
<td></td>
</tr>
<tr>
<td>Alfuzosin/boceprevir and telaprevir</td>
<td>Combination is contraindicated; may result in hypotension</td>
</tr>
<tr>
<td>Antiarrhythmics/boceprevir and telaprevir</td>
<td>The serum concentration of the antiarrhythmics may increase with concomitant administration; use with caution and careful monitoring</td>
</tr>
<tr>
<td>Anticonvulsants/boceprevir and telaprevir</td>
<td>Boceprevir is contraindicated with phenytoin, carbamazepine, and phenobarbital due to loss of virologic response; telaprevir concentrations may decrease; concentrations of phenytoin, carbamazepine, or phenobarbital may be altered</td>
</tr>
<tr>
<td>Antidepressants/boceprevir and telaprevir</td>
<td>Serum concentrations of trazodone and desipramine may increase; the concentration of escitalopram decreases when administered with telaprevir</td>
</tr>
<tr>
<td>Antifungals/boceprevir and telaprevir</td>
<td>Serum concentrations of the antifungal and boceprevir or telaprevir may increase; do not exceed 200 mg/day of itraconazole or ketoconazole</td>
</tr>
<tr>
<td>Benzodiazepines/boceprevir and telaprevir</td>
<td>Concentrations of alprazolam and midazolam may increase; triazolam and oral midazolam are contraindicated</td>
</tr>
<tr>
<td>Bosentan/boceprevir and telaprevir</td>
<td>Serum concentrations of bosentan may increase</td>
</tr>
<tr>
<td>CCBs/boceprevir and telaprevir</td>
<td>CCB concentrations may increase; coadminister with caution</td>
</tr>
<tr>
<td>Colchicine/boceprevir and telaprevir</td>
<td>Do not administer the combination in patients with renal or hepatic impairment; dose modification of colchicine is recommended</td>
</tr>
<tr>
<td>Corticosteroids/boceprevir and telaprevir</td>
<td>Concomitant use of dexamethasone with boceprevir or telaprevir may result in reduced serum concentrations of boceprevir or telaprevir; the concentrations of inhaled corticosteroids (budesonide/fluticasone) may be increased with boceprevir or telaprevir; coadministration of telaprevir with systemic corticosteroids is not recommended</td>
</tr>
</tbody>
</table>
### Warnings

As described in the drug interaction table above, oral contraceptives may be less effective when combined with these agents. Women should be counseled to use 2 effective forms of birth control while taking these medications. Both agents have also been reported to cause anemia. Boceprevir has also been reported to cause neutropenia.

**Telaprevir**

Severe skin reactions including Stevens-Johnson Syndrome and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) have been reported with telaprevir; discontinue telaprevir immediately if this occurs.Telaprevir is not recommended for patients with moderate or severe hepatic impairment or those with decompensated liver.

<table>
<thead>
<tr>
<th>Interacting Medications</th>
<th>Interaction Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin/boceprevir and telaprevir</td>
<td>The serum concentration of digoxin may increase with concomitant administration; use with caution and careful monitoring</td>
</tr>
<tr>
<td>Ergot derivatives/boceprevir and telaprevir</td>
<td>Combination is contraindicated; ergot toxicity may occur</td>
</tr>
<tr>
<td>HIV protease inhibitors/boceprevir and telaprevir</td>
<td>Serum concentrations of boceprevir and telaprevir may be decreased; serum concentrations of the HIV protease inhibitors may also be altered</td>
</tr>
<tr>
<td>HMG-CoA reductase inhibitors/boceprevir and telaprevir</td>
<td>Use of lovastatin or simvastatin is contraindicated with boceprevir and telaprevir (atorvastatin is also contraindicated with telaprevir due to the risk of rhabdomyolysis)</td>
</tr>
<tr>
<td>Immunosuppressants/boceprevir and telaprevir</td>
<td>Serum concentrations of cyclosporine, sirolimus, and tacrolimus increase with concomitant boceprevir or telaprevir</td>
</tr>
<tr>
<td>Macrolide antibiotics/boceprevir and Telaprevir</td>
<td>Concentrations of the antibiotic may increase; use caution with those that prolong the QT interval</td>
</tr>
<tr>
<td>Methadone/boceprevir and telaprevir</td>
<td>Concentrations of methadone decreased when administered with telaprevir; the combination of boceprevir with methadone or buprenorphine has not been studied</td>
</tr>
<tr>
<td>Oral contraceptives/boceprevir and telaprevir</td>
<td>Serum estrogen concentrations decreased with either agent; drospirenone concentrations increased with boceprevir and concomitant use is contraindicated</td>
</tr>
<tr>
<td>PDE5 inhibitors/boceprevir and telaprevir</td>
<td>Increased concentrations of sildenafil, tadalafil, and vardenafil are expected; dosage adjustments may be necessary; use for pulmonary arterial hypertension is contraindicated</td>
</tr>
<tr>
<td>Pimozide/boceprevir and telaprevir</td>
<td>Do not coadminister; life-threatening arrhythmias may occur</td>
</tr>
<tr>
<td>Reverse transcriptase inhibitors/boceprevir and telaprevir</td>
<td>Serum concentrations of boceprevir and telaprevir decreased when administered with efavirenz (efavirenz concentrations decreased as well with telaprevir); the combination should be avoided; tenofovir concentrations increased with telaprevir coadministration</td>
</tr>
<tr>
<td>Rifabutin and rifampin/boceprevir and telaprevir</td>
<td>Do not coadminister; concentrations will increase along with a decrease in boceprevir and telaprevir concentrations</td>
</tr>
<tr>
<td>Salmeterol/boceprevir and telaprevir</td>
<td>Concomitant use of either agent with salmeterol is not recommended due to increased risk of CV events</td>
</tr>
<tr>
<td>St. John’s Wort/boceprevir and telaprevir</td>
<td>Do not coadminister; loss of virologic response may occur</td>
</tr>
<tr>
<td>Warfarin/boceprevir and telaprevir</td>
<td>Serum concentrations of warfarin may be altered; carefully monitor INR</td>
</tr>
</tbody>
</table>

CCB(s)=calcium channel blocker(s); CV=cardiovascular; HIV=human immunodeficiency virus; HMG-CoA=3-hydroxy-3-methylglutaryl-coenzyme A; INR=international normalized ratio; NRTIs=nucleoside/nucleotide reverse transcriptase inhibitors; PDE5=phosphodiesterase type 5.
Telaprevir may cause rash; discontinue use if rash worsens or systemic symptoms develop.

**Adverse Effects**

Anemia and gastrointestinal adverse effects are common with telaprevir and boceprevir. Anemia was more common when either telaprevir or boceprevir were administered with pegylated interferon/ribavirin treatment than with pegylated interferon/ribavirin alone. Up to 50% of patients in trials with boceprevir reported anemia. The manufacturers of both agents recommend routine hemoglobin monitoring. Dysguesia (distortion of the sense of taste) has also been reported with both agents; however, it appears to be more common with boceprevir. Telaprevir has been more commonly associated with rash than boceprevir. Rash occurred in over half of the telaprevir-treated patients in clinical trials compared with less than 20% of patients treated with boceprevir. Severe rash has also occurred in telaprevir-treated patients. Patients with rash progression or systemic symptoms should discontinue telaprevir.

**Pregnancy and Lactation**

Although telaprevir and boceprevir are pregnancy category B, they are given in combination with ribavirin, a drug that is category X. Ribavirin has been shown to cause birth defects and fetal deaths. Extreme caution should be taken to prevent pregnancy in women being treated for hepatitis C. Women should discontinue nursing prior to treatment with telaprevir or boceprevir.

**Counseling the patient**

There are several factors that should be discussed with patients who are beginning treatment for hepatitis C. The risk of birth defects reported with ribavirin should be discussed with all women and men who are starting treatment. Not only should women use 2 methods of birth control while being treated, female partners of men who are taking ribavirin are at risk should they become pregnant.

It is recommended that telaprevir be taken with a meal or snack containing 20 grams of fat. Some patients with Hepatitis C may not have an appetite so it is important for the pharmacist to provide some guidance on what foods can be taken that are higher in fat.

**Role in therapy**

These agents in combination with standard therapy (peginterferon and ribavirin) have shown improved outcomes compared to standard therapy increasing SVR rates to ~75%, both for treatment-naïve patients and patients who have relapsed or not responded to previous therapy. There are no head to head comparisons of telaprevir and boceprevir. Physicians must consider the efficacy as reported in the clinical trials as well as the potential adverse effect profile of the agents when making a choice.

**FIDAXOMICIN (DIFICID™)**

Fidaxomicin is a macrocyclic antibiotic that received FDA approval for the treatment of *C. difficile* associated diarrhea. It is the first new agent for *C. difficile* diarrhea in 25 years. There has been an increase in the incidence and severity of *C. difficile* infection due to the overuse of broad spectrum antibiotics. *C. difficile* infection is the most common form of infectious diarrhea in the hospital and other institutional settings. Up to 40% of diarrhea reported in nursing homes is caused by *C. difficile*.

**Pharmacology/Pharmacokinetics**

Fidaxomicin exerts bactericidal activity by inhibiting transcription through the sigma subunit of RNA polymerases and terminating RNA synthesis. The antibiotic exhibits activity against gram positive aerobes and anaerobes with no activity against gram negative bacteria, including *Bacteroides spp*. Fidaxomicin offers a post-antibiotic effect between 6 to 10 hours against *C. difficile*.

**Indications**

Fidaxomicin is approved for the treatment of *C. difficile* associated diarrhea.

**Dosing**

The recommended dose is 200mg of fidaxomicin by mouth twice daily for 10 days with or without food.
**Contraindications**

There are no contraindications to the use of fidaxomicin.\(^{17}\)

**Drug Interactions**

No clinically significant drug-drug interactions are reported with fidaxomicin.\(^{17}\)

**Warnings**

Fidaxomicin should not be used for systemic infections.\(^ {17,18}\) Because of the risk of drug resistance, fidaxomicin should only be used in documented or strongly suspected infections of *C. difficile*.

**Adverse Effects**

The most frequent adverse reaction during clinical trials that contributed to subject withdrawal was vomiting which occurred in 0.5% of patients in both the fidaxomicin and vancomycin groups.\(^ {14,17}\) Gastrointestinal symptoms were the most common adverse reaction reported in clinical trials and the incidence did not differ between fidaxomicin and vancomycin treated patients. These symptoms included nausea (11%), vomiting (7%), and abdominal pain (6%).

**Pregnancy and Lactation**

Fidaxomicin is pregnancy category B.\(^ {17}\) Its use should be reserved for cases where the benefit outweighs the risk to the fetus. It is not known if fidaxomicin is excreted into human milk.

**Counseling the patient**

Pharmacists should remind patients that fidaxomicin can be taken without regard to meals. Because of the risk of drug resistance, patients should be counseled about taking the entire course of treatment with fidaxomicin. Patients often want to stop antibiotic treatment when their symptoms improve, but they should take the full course of therapy to prevent relapse of diarrhea or the development of resistant organisms.

**Role in therapy**

Fidaxomicin is a safe and effective antibiotic for the treatment of *C. difficile* infections.\(^ {18}\) It shows promise in reducing recurrences compared to vancomycin. It has not been evaluated compared to metronidazole, which is the current standard for mild to moderate *C. difficile* infections. Pharmacists may see this agent prescribed in nursing home patients.

**ROFLUMILAST (DALIRESP™)**

Roflumilast is the first agent in a new drug class for COPD treatment. It is an inhibitor of the enzyme called phosphodiesterase type 4 (PDE-4). It was approved by the FDA on March 1, 2011. This drug was approved with a REMS that requires patients to receive a medication guide detailing the potential risk of mental changes including suicidality and unexplained weight loss.

**Pharmacology/Pharmacokinetics**

Roflumilast is a selective inhibitor of phosphodiesterase 4 (PDE4).\(^ {19,20}\) Inhibition of PDE4 activity leads to accumulation of intracellular cyclic AMP. The specific mechanism of action of roflumilast is not known; however, it is thought to be due to its effects of increased intracellular cyclic AMP in lung cells. Roflumilast is well absorbed after oral administration. It is approximately 99% and 97%, plasma protein bound. The half-life is 17 hours for roflumilast and 30 hours for the N-oxide metabolite. Roflumilast is extensively metabolized in the liver to an active metabolite, rolfumilast-N-oxide. Both the parent drug and its metabolite are excreted in the urine.

**Indications**

Roflumilast is indicated to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.\(^ {19}\) Roflumilast is not a bronchodilator and should not be used for acute bronchospasm.

**Dosing**

The dose of roflumilast is 500 mcg orally once a day.\(^ {19}\) The dose may be given without regard to meals. No dose adjustment is needed in patients with renal impairment.
Contraindications
Roflumilast is contraindicated in moderate to severe liver disease.19

Drug Interactions
Roflumilast may interact with inhibitors of CYP3A4 or dual inhibitors of CYP3A4 and CYP1A2 (e.g., erythromycin, ketoconazole, fluvoxamine, enoxacin, and cimetidine).14,19 Concurrent use can result in elevated levels of roflumilast.

Warnings
Do not use roflumilast for acute bronchospasm as it is not a bronchodilator.20 Patients have reported psychiatric side effects including suicidality with roflumilast.19 A total of 3 patients attempted suicide (1 death) while taking roflumilast during clinical trials. Avoid the use of this agent in patients with a history of suicidal thoughts or behaviors and in patients with depression. Other reported adverse psychiatric effects included anxiety, insomnia, and depression. Moderate weight loss (5 to 10% of body weight) was reported in 20% of patients in clinical trials, while 7% of patients reported severe weight loss (>10% body weight).

Adverse Effects
In addition to the suicidality and weight loss, other adverse effects that occurred in > 2% of patients include diarrhea, nausea, headache, back pain, insomnia, dizziness and poor appetite.4,19 Side effects that occurred in 1 to 2% of patients included abdominal pain, vomiting, rhinitis, muscle spasms, tremor, anxiety and depression.

Pregnancy and Lactation
Roflumilast is pregnancy category C.19 Its use in pregnancy should be restricted to those patients where the benefits outweigh the risks. Roflumilast should not be used during breastfeeding as the drug and its metabolites are excreted into breast milk.

Counseling the Patient
Patients should be reminded that this medication is not a bronchodilator and will not be useful in acute bronchospasm. The pharmacist should counsel the patient on treatment of acute bronchospasm. When a patient is started on roflumilast, the pharmacist should discuss the risk of suicidal thoughts and behavior. Since some people may develop mood or behavior problems including suicidal thoughts, insomnia, anxiety and depression, the pharmacist should discuss these symptoms with the patient and encourage them to discuss any changes in behavior or thoughts with the pharmacist or physician. Patients should be alerted to the possibility of significant weight loss with this drug. Patients should weigh themselves regularly and talk to the doctor if their weight loss is significant.

Role in therapy
Roflumilast is approved for use in patients with severe COPD associated with chronic bronchitis that have flares.19,20 It does not appear to have a role in COPD that primarily involves emphysema. Because of the potential adverse effects reported with this agent, its use will be reserved for patients who have not responded to standard therapy.

INDACATEROL (ARCAPTA™)

The GOLD guidelines outline the treatment of COPD through management of 4 components; assessment and monitoring, reduction of risk factors, management of stable disease, and management of exacerbations.21 Management of stable COPD is primarily accomplished with the use of long-acting bronchodilators (primarily beta2-agonists and anticholinergic agents). Indacaterol is the first once daily long-acting beta agonist approved by the FDA on July 1, 2011.

Pharmacology/Pharmacokinetics
Indacaterol stimulates beta-adrenergic receptors of adenyl cyclase, resulting in an increase in c-AMP levels, and relaxation of bronchial smooth muscles.22 After inhalation, indacaterol reaches steady state in 12 to 15 days. The half-life of indacaterol is 40 to 56 hours. Indacaterol is excreted primarily in the feces as the parent drug and the hydroxylated metabolites.

Indications
Indacaterol is approved for maintenance treatment of bronchoconstriction in patients with COPD, including
chronic bronchitis or emphysema. It is not indicated to treat acute deterioration of COPD. It is not approved for use in asthma.

**Dosing**
Indacaterol is administered using a custom inhaler. The dose is 75 mcg inhaled once a day. Do not swallow the indacaterol capsule. They should only be used with the Neohaler device. Dose adjustment is required for patients with renal impairment or mild to moderate hepatic impairment.

**Contraindications**
Long-acting beta_2-agonists increase the risk of asthma-related death. Safety and efficacy of these agents have not been established in patients with asthma, and are contraindicated in patients with asthma without use of a long-term asthma control medication.

**Drug Interactions**
As with other long acting beta-agonists, indacaterol may interact with other drugs.

<table>
<thead>
<tr>
<th>Interacting Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoamine oxidase inhibitors, tricyclic antidepressants, and other drugs that may prolong the QT interval</td>
<td>Effects of beta_2-agonists on the cardiovascular system may be potentiated, use with extreme caution</td>
</tr>
<tr>
<td>Beta-adrenergic blockers</td>
<td>May inhibit the pulmonary effects of beta_2-agonists and also cause bronchospasm</td>
</tr>
<tr>
<td>Loop and thiazide diuretics</td>
<td>Hypokalemia may be worsened</td>
</tr>
<tr>
<td>Xanthine derivatives, steroids, or diuretics</td>
<td>May potentiate the hypokalemic effects of indacaterol</td>
</tr>
<tr>
<td>Other agents with adrenergic actions</td>
<td>May potentiate the effects of beta_2-agonists</td>
</tr>
</tbody>
</table>

**Warnings**
Do not use more than the recommended dose and do not administer more than once daily. More frequent use can result in cardiovascular effects and death.

**Adverse Effects**
Adverse effects reported with indacaterol include paroxysmal bronchospasm that may be life-threatening, increased heart rate, angina pectoris, and hypertension. Other adverse effects reported in > 2% of patients include hyperglycemia, sinusitis, muscle spasm and pain, and peripheral edema.

**Pregnancy and Lactation**
Indacaterol is pregnancy category C. The use of this agent should be reserved for those patients where the benefits outweigh the risks. It is not known if indacaterol is excreted into human milk.

**Counseling the patient**
The pharmacist should counsel the patient about the proper use of the indacaterol inhaler. Reinforce that the indacaterol inhaler is not a rescue inhaler for acute bronchospasm. Be sure that the patient has a short-acting beta agonist rescue inhaler available and understands how to use it. Have the patient demonstrate the proper use of both the indacaterol inhaler and their rescue inhaler.

**Role in therapy**
In COPD, the long-acting bronchodilators are recommended over short-acting agents. Some studies suggest that there may be a preference for a long-acting inhaled anticholinergic agent rather than a long-acting beta_2-agonist. Indacaterol is the first once daily inhaled long-acting beta_2-agonist available which may be more desirable for some patients. No trials have compared indacaterol to other long acting beta_2-agonists for efficacy or safety.
CASE SCENARIO

Mrs. Johnson is a frail, 63 year old woman who comes to the pharmacy with a prescription for roflumilast (Daliresp). She is very confused about why she is taking this medication and wants to know if she can now throw out her inhalers. Her doctor told her this will help with her COPD “spells”. What important facts do you need to review when filling this prescription?

You explain to Mrs. Johnson that the roflumilast is a new drug that is used to help prevent flares of her COPD. You discuss with her that you understand sometimes she has periods where she becomes more short of breath and her bronchitis acts up. You explain that taking this medication each day will help ease those flares. It is a prevention medication. You further explain that she will still need to continue her bronchodilator and should use that for acute bronchospasm or flare. You explain that she is to take one dose each day of the roflumilast to help prevent flares.

You review with Mrs. Johnson that some people may develop mood or behavior changes while on this medication. You discuss openly with her that there have been reports of patients having thoughts of suicide and explain to her that she should talk to you if this occurs or talk to her doctor. You also discuss the possibility of significant weight loss when taking roflumilast. You ask Mrs. Johnson to make a chart of her weight each week and alert you or the doctor if she experiences significant weight loss. You ask Mrs. Johnson to explain to you how she is supposed to take the roflumilast and what she should be alert for. You also have her demonstrate that she understands how to use her inhalers for flares.

REFERENCES

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?
   - Yes
   - No

2. Was the program independent & non-commercial
   - Yes
   - No

3. Relevance of topic
   - Poor
   - Average
   - Excellent

4. What did you like most about this lesson?

5. What did you like least about this lesson?

Please Select the Most Correct Answer(s)

1. Which medication should be taken with at least 20 Gms of fat at each dose?
   - A. Boceprevir
   - B. Fidaxomicin
   - C. Telaprevir
   - D. Azilsartan

2. Boceprevir & telaprevir are given in combination with:
   - A. Peginterferon alfa & ribavirin
   - B. Peginterferon alfa alone
   - C. Ribavirin & vilazodone
   - D. None of these

3. Salmeterol is safe to administer in combination with telaprevir.
   - A. True
   - B. False

4. Which of these may cause mental changes & weight loss?
   - A. Ticagrelor
   - B. Arcapta
   - C. Roflimilast
   - D. Dificid

5. Which drug is the 1st new agent for C. difficile diarrhea in 25 years.
   - A. Dificid
   - B. Tegretol
   - C. Daliresp
   - D. Diarterm

6. The most frequent adverse reaction during clinical trials with fidaxomicin that caused subjects to withdraw was:
   - A. Nausea
   - B. Diarrhea
   - C. Headache
   - D. Shortness of breath

7. Fidaxomicin has a post antibiotic effect between 6 & 10 hours against:
   - A. True
   - B. False

8. Indacaterol is approved for:
   - A. Acute deterioration of COPD
   - B. Asthma
   - C. Maintenance for bronchoconstriction
   - D. All of these

9. How is hepatitis C infection primarily spread?
   - A. Infectious blood
   - B. Razors
   - C. Toothbrushes
   - D. Airborne

10. What can be attributed to increase the occurrence of C. diff?
    - A. Overuse of broad spectrum antibiotics
    - B. Patient weakness
    - C. Poor diet
    - D. Obesity
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