West Virginia Medicaid
Pharmacy Solutions

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West Virginia Medicaid Pharmacy Department

http://www.dhhr.wv.gov/bms/Pharmacy

Provider Services

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304-348-3360
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Pharmacy Help Desk& Pharmacy Prior Authorization (Rational Drug Therapy Program)

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For a copy of the most recent preferred drug list, visit:
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SMAC Review Form:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/smac.aspx
Please refer questions to Magellan at 1-800-763-7382 or e-mail to StateSMACProgram@magellanhealth.com

Review of the Updated ACC Cholesterol Guidelines

It's a new year and with every new year comes the ever popular, easy to make and even easier to break New Year's Resolutions. One of the more common resolutions is to exercise more, eat healthier and lose weight. For many people this resolution is due to a health risk such as having high cholesterol, increasing their risk for atherosclerotic cardiovascular disease (ASCVD). Unfortunately, eating healthy and exercising alone isn't always a successful method of lowering cholesterol and the associated risk of ASCVD.

In 2013 the original American College of Cardiology (ACC)/American Heart Association (AHA) guidelines for the treatment of blood cholesterol were published. These guidelines recommended the use of statin therapy in 4 patient groups:

1. Patients with clinical atherosclerotic cardiovascular disease (ASCVD).
2. Patients with low-density lipoprotein cholesterol (LDL-C) levels of 190 mg/dL or higher (not due to secondary modifiable causes, such as medications, metabolic disorders, underlying disease, or poor diet).
3. Patients aged 40 to 75 years without ASCVD, but with type 2 diabetes mellitus (T2DM) and an LDL-C level of 70 mg/dL to 189 mg/dL.
4. Patients aged 40 to 75 years without ASCVD or T2DM, but with an LDL-C level of 70 mg/dL to 189 mg/dL and an estimated 10-year ASCVD risk of 7.5% or higher (estimated using the pooled risk cohort equation).

The guidelines also subdivided statin therapy into 2 groups: high-intensity and moderate-intensity therapy. High-intensity therapy was intended to lower LDL-C by ≥50% and moderate-intensity to lower LDL-C by 30% to <50%. High-intensity therapy was listed as being the desired approach for most patients with moderate-intensity therapy considered sufficient for use in 2 patient groups:

1. Patients older than 75.
2. Patients aged 40 to 75 with LDL-C levels <190 mg/dl, no existing ASCVD, and a 10-year risk of ASCVD <7.5%.

Unlike a lot of disease states, there have been new developments in the treatment of high cholesterol including FDA approval of non-statin therapies and new clinical evidence on the use of existing therapies. As a result, the ACC guidelines were updated in 2016 to include the proper use of statins and these new therapy options.

The updated guidelines still recommend the use of statin therapy in the 4 patient groups identified in the 2013 guidelines. The main change is the dosing breakdown. The 2013 guidelines separated statin therapy in high-intensity dosing (≥50% reduction in LDL-C) and moderate-intensity dosing (30 to 50% LDL-C reduction). The updated guidelines break the recommended statin dosing into 3 groups. A breakdown of the dosing recommendations is listed in the chart below.

Daily dosage lowers LDL-C ≥ 50%	Daily dosage lowers LDL-C 30% to 50%	Daily dosage lowers LDL-C < 30%
atorvastatin 40 to 80 mg	atorvastatin 20 mg	simvastatin 10 mg
rosuvastatin 40 mg	rosuvastatin 10 mg	pravastin 10 to 20 mg
	simvastatin 20 to 40 mg	lovastatin 20 mg
	pravastatin 80 mg	fluvastatin 20 to 40 mg
	lovastatin 40 mg	pitavastatin 1 mg
	fluvastatin XL 80 mg	
	fluvastatin 40 mg BID	
	pitavastatin 2 to 4 mg	

Unfortunately, some patients are not able to tolerate statin therapy. Signs of statin intolerance include: muscle pain or cramps, muscle inflammation and elevated creatine kinase (marker of muscle injury), liver toxicity and muscle toxicity known as rhabdomyolysis. Below are some methods for diagnosing statin intolerance:

1. Perform a full medical evaluation
2. Perform a blood test to identify any abnormalities (high creatine kinase, liver damage, etc.)
3. Assess for a family history of statin intolerance
4. Conduct a genetic test for possibility of statin intolerance markers
5. Conduct a muscle biopsy for muscle testing
6. Provide and assess a patient symptom questionnaire
7. Conduct a muscle strength test

Factors that may increase the risk for statin intolerance are:

1. 80 years or older
2. Female
3. Asian ethnicity
4. Certain preexisting conditions, such as neuromuscular or liver conditions
5. Excessive alcohol consumption
6. Excessive exercise
7. Grapefruit juice consumption

There a several treatment options when dealing with statin intolerance:

1. Lower the statin dose
2. Decrease number of days the statin dose is taken, i.e. take every other day instead of every day
3. Change to a different statin
4. Change to an alternative drug therapy

The 2016 ACC guidelines added the use of non-statin therapies ezetimibe, bile acid sequestrants and PCSK9 inhibitors – alirocumab (Praluent) and evolocumab (Repatha) to their treatment algorithms. Niacin has been used in some patients in the past but current evidence doesn't show any clinical benefit and is therefore no longer recommended. Ezetimibe is an option for all patient groups and should be considered first-line non-statin therapy except in patients with a baseline LDL-C $\geq$190 mg/dl. Bile acid sequestrants are generally reserved as an option in patients who are intolerant to or have an inadequate response with ezetimibe and have a fasting triglyceride level <300 mg/dl. PCSK9 inhibitors are not recommended for all patient groups. Only patients taking maximally tolerated statin therapy who have ASCVD, or patients without ASCVD and a baseline LDL-C levels $\geq$190 mg/dl are potential candidates for PCSK9 therapy. Ezetimibe should be considered before the use of a PCSK9 inhibitor except in patients with a baseline LDL-C level $\geq$190 mg/dl.

The new guidelines recommend a non-statin treatment approach based on the use of 6 patient groups. Below is a table from the guidelines containing the 6 patient groups, goal of therapy and treatment options/recommendations.

Patient Population	**Goal**	**Pharmacologic Options**
Patients with stable clinical ASCVD without comorbidities who are taking a statin for secondary prevention	≥50% reduction in LDL-C, or optionally, an LDL-C level <100 mg/dL (provided that the patient is on a maximally tolerated statin)	Ezetimibe should be used first, with later consideration of a PCSK9 inhibitor alone or in combination with ezetimibe
Patients with clinical ASCVD with comorbidities who are taking a statin for secondary prevention	≥50% reduction in LDL-C, or optionally, an LDL-C level <70 mg/dL or non–HDL-C level <100 mg/dL (provided that the patient is on a maximally tolerated statin)	Ezetimibe should be used first, with later consideration of a PCSK9 inhibitor alone or in combination with ezetimibe
Patients with clinical ASCVD with baseline LDL-C levels ≥190 mg/dL who are taking a statin for secondary prevention	≥50% reduction in LDL-C, or optionally, an LDL-C level <70 mg/dL (provided that the patient is on a maximally tolerated statin)	Patients initiating nonstatin therapy have the option of initiating a PCSK9 inhibitor or ezetimibe. Bile acid sequestrants are a second-line option after ezetimibe in patients who are intolerant to ezetimibe and have triglyceride levels <300 mg/dL.
Patients without clinical ASCVD, but with baseline LDL-C levels ≥190 mg/dL not due to secondary causes taking a statin for primary prevention	≥50% reduction in LDL-C, or optionally, an LDL-C level <100 mg/dL (provided the patient is on a maximally tolerated statin)	Patients initiating nonstatin therapy have the option of initiating a PCSK9 inhibitor or ezetimibe. Bile acid sequestrants are a second-line option after ezetimibe in patients who are intolerant to ezetimibe and have triglyceride levels <300 mg/dL.

Patients aged 40 to 75 years without clinical ASCVD, but with diabetes and baseline LDL-C levels 70 to 189 mg/dL taking a statin for primary prevention	≥50% reduction in LDL-C, or optionally, an LDL-C level <100 mg/dL or non–HDLC level <130 mg/dL (provided the patient is on a maximally tolerated statin)	Patients have the option of initiating either ezetimibe (preferred) or bile acid sequestrants as a second-line option after ezetimibe in those who are intolerant to ezetimibe and have triglyceride levels <300 mg/dL. If bile acid sequestrants are used, colesevelam should be considered due to its modest HbA1C-reducing effects.
Patients aged 40 to 75 years without clinical ASCVD or diabetes, but with baseline LDL-C levels 70 to 189 mg/dL, and a 10-year ASCVD risk ≥7.5% taking a statin for primary prevention	<30% reduction in LDL-C, or optionally, if they do not have an LDL-C level <100 mg/dL on a moderate-intensity statin OR If patients have high-risk markers[b]	After attempting high-intensity statin therapy, patients have the option of initiating either ezetimibe (preferred) or bile acid sequestrants as a second-line option after ezetimibe in those who are intolerant to ezetimibe and have triglyceride levels <300 mg/dL.

Here are a few key points based on the new 2016 ACC Cholesterol Guidelines:

- Stain therapy is still considered to be first line option in most patients
- Niacin is no longer recommended
- Bile acid sequestrants may be considered as second-line therapy after ezetimibe in patients with fasting triglyceride levels <300 mg/dL.
- Ezetimibe is an option for all patient groups and should be considered the first-line non-statin therapy in patients with ASCVD and a baseline LDL-C level <190 mg/dL.
- Patients with ASCVD are candidates for PCSK9 inhibitor therapy
- Patients without ASCVD with a baseline LDL-C level ≥190 mg/dl are candidates for PCSK9 inhibitor therapy.

In conclusion, statin therapy is still recommended as first line therapy in the treatment of cholesterol disease. Since statin therapy alone isn't always successful and some patients are statin intolerant, other options are needed. The new ACC Guidelines provide valuable information and treatment recommendations on when and where these non-statin products should be used in the management of cholesterol disease.

Upcoming PDL Changes

The following changes will be made to the Preferred Drug List (PDL), effective April 1, 2018, pending recommendation and/or approval by the P&T Committee, BMS, and Secretary of DHHR.

For a comprehensive PDL, refer to http://www.medicaid.ms.gov/providers/pharmacy/preferred-drug-list/.

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**RECOMMENDED for NON-PREFERRED STATUS**
ANALGESICS, NARCOTIC LONG ACTING (NON-PARENTERAL)	MORPHABOND ER (morphine sulfate)
ANTIEMETICS - CANNABINOIDS	SYNDROS (dronabinol)
ANTIMIGRAINE AGENTS, TRIPTANS	eletriptan
ANTIPARKINSON'S AGENTS - OTHER ANTIPARKINSON'S AGENTS	XADAGO (safinamide)
BONE RESORPTION SUPPRESSION AND RELATED AGENTS	TYMLOS (abaloparatide)
CYTOKINE & CAM ANTAGONISTS, ANTI-INFS	RENFLEXIS (infliximab)
CYTOKINE & CAM ANTAGONISTS, OTHERS	KEVZARA (sarilumab)
CYTOKINE & CAM ANTAGONISTS, OTHERS	TREMFYA (guselkumab)
GLUCOCORTICOIDS, INHALED	ARMONAIR (fluticasone)
GLUCOCORTICOIDS, INHALED – GLUCOCORTICOID/BRONCHODILATOR COMBINATIONS	fluticasone/salmeterol
HEPATITIS C TREATMENTS	VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)
IMMUNOMODULATORS, ATOPIC DERMATITIS	DUPIXENT (dupilumab)
LIPOTROPICS, STATINS – STATIN COMBINATIONS	simvastatin/ezetimibe
NSAIDS, NON-SELECTIVE	LODINE (etodolac)
STIMULANTS AND RELATED AGENTS, AMPHETAMINES	MYDAYIS (dextroamphetamine/amphetamine)
VASODILATORS, CORONARY	GONITRO POWDER (nitroglycerin)