P&T Committee Meeting Minutes
GHP Family-Healthy Connect Business
August 24, 2015

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Beverly Blaisure, MD
Kristen Bender, Pharm.D. – via phone	Keith Boell, DO
Holly Bones, Pharm.D. – via phone	John Flaherty, Pharm.D.
Dean Christian, MD	Thomas Morland, MD
Kimberly Clark, Pharm.D.	Jonas Pearson, MS, RPh
Jamie Dodson, RPh	James Schuster, MD
Tricia Heitzman, Pharm.D.	Michael Spishock RPh
Michelle Holt-Macey, Pharm.D. – via phone	Elaine Tino, CRNP
Jonathan Hoot, Pharmacy Student	Steve Tracy, Pharm.D
Kristi Juskiewicz, Pharm. D. – via phone	
Steven Kheloussi, Pharm.D. – via phone	
Phillip Krebs, R.EEG T.	
Lisa Mazonkey, RPh– via phone	
Daniel McConnell, Pharm.D., RPh	
Perry Meadows, MD	
Mariette Njei, Pharmacy Resident	
Kristen Scheib, Pharm. D. – via phone	
William Seavey, Pharm.D. – via phone	
Richard Silbert, MD – via phone	
Aubrielle Smith, Pharmacy Student – via phone	
Todd Sponenberg, Pharm.D., RPh	
Kevin Szczecina, RPh – via phone	
Lori Zaleski, RPh – via phone	

Call To Order:
Dr. Bret Yarczower called the meeting to order at 1:00 p.m., Monday, August 24, 2015.

DRUG REVIEWS:

Toujeo **Steven Kheloussi**
(insulin glargine)

Steven Kheloussi provided a review of Toujeo to the committee for consideration as a pharmacy benefit. Toujeo is indicated to improve glycemic control in adults with diabetes mellitus.

*Toujeo is not indicated in the treatment of diabetic ketoacidosis.

Toujeo is long-acting insulin that works by stimulating peripheral uptake of glucose by skeletal muscle and fat, thereby lowering blood glucose. It also lowers blood glucose through the inhibition of hepatic glucose production, lipolysis, proteolysis and enhances protein synthesis.

Formulary alternatives: Lantus Solostar, Lantus, Levemir, Levemir Flextouch

Proposed Clinical Recommendations: Toujeo has been shown to be a safe and effective basal insulin alternative and should be added to the GHP Family-Healthy Connect formulary with prior authorization for members under the age of 18 years with the following criteria:

- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that use of Toujeo has been shown to be safe and effective in patients under the age of 18 years.

Clinical Discussion: Toujeo (insulin glargine) is a long acting insulin used in the treatment of diabetes mellitus. Toujeo has the same active ingredient as Lantus but it is more potent. Toujeo has have been shown to be non-inferior to Lantus in achieving glycemic goal, but patients using Toujeo require higher doses of basal insulin compared to patients using Lantus. Toujeo is a subcutaneous injection available as a disposable prefilled Solostar pen containing 450 units/1.5mL (300 units/mL). Toujeo pens are available in packages of 3 or 5 pens. Lantus can be used in patients 6 years or older while Toujeo is indicated for patients 18 years of age or older.

Clinical Outcome: Jamie Dodson made a motion to accept the recommendation as written. Dr. Perry Meadows seconded the motion. None were opposed.

Proposed Financial Recommendations: Toujeo should be added to the GHP Family-Healthy Connect formulary with prior authorization for patients under the age of 18. No further criteria should apply.

Financial Discussion: Not all FDA approved NDC's are currently available commercially. The cost per unit decreases as the units per package size increases.

Financial Outcome: Jamie Dodson made a motion to accept the recommendations as written. Kimberly Clark seconded the motion. None were opposed.

Approved Recommendations: Toujeo will be added to the GHP Family-Healthy Connect formulary. The following prior authorization criteria will apply to members under the age of 18:

- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that use of Toujeo has been shown to be safe and effective in patients under the age of 18 years.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Praluent (alirocumab)	**Steven Kheloussi**

Steven Kheloussi provided a review of Praluent to the committee for consideration as a pharmacy benefit. Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C. Limitation of Use: The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Alirocumab is a human monoclonal antibody that binds to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to the LDL receptor (LDLR) on the surface of hepatocytes to promote LDLR degradation within the liver. LDLR is the primary receptor that clears circulating LDL, therefore the decrease in LDLR levels by PCSK9 results in higher blood levels of LDL-C. By inhibiting the binding of PCSK9 to LDLR, alirocumab increases the number of LDLRs available to clear LDL, thereby lowering LDL-C levels.

Formulary alternatives: none

Proposed Clinical Recommendations: It is recommended that Praluent not be added to the GHP Family-Healthy Connect formulary at this time. A Praluent-specific policy should be created, with the following prior authorization requirements:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia **AND** either:
    - Genetic testing to confirm a mutation in the LDL receptor gene **OR**
    - Medical record documentation of definite HeFH (score > 8) on the diagnostic criteria scoring system (Table 1) as defined by the ESC/EAS guidelines and the World Health Organization **AND**
- Prescription must be written by a cardiologist **AND**
- Medical record documentation of a baseline LDL at the start of PCSK9 therapy **AND**
- Medical record documentation that the patient is > 18 years of age **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to high-intensity statin therapy, including atorvastatin 40 mg or 80 mg or Crestor 20 mg or 40 mg, or the highest tolerable dose **AND**
- If a retrial of statins is not contraindicated (i.e., in patients with mild to moderate myalgia or myopathy or LFTs > 3x ULN that return to baseline upon discontinuation), medical record documentation of two retrials with lower doses or alternative statins is required **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation an inability to achieve and maintain an LDL cholesterol level at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with a

combination of medications, diet, and exercise.

Definitions:

- Therapeutic failure to statins and/or Zetia – inability to reach target LDL Goals (<100 mg/dL or <70 mg/dL based on patient risk) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
- Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).
- Intolerance to statins – increased LFTs, rhabdomyolysis, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms)
- Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with Tx and/or children <18 with LDL-C >95th centile	2
Clinical history	Patient has premature CAD*	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tx	6
	Arcus cornealis below the age of 45 years	4
LDL-C	>8.5 mmol/L (more than ~330 mg/dL)	8
	6.5-8.4 mmol/L (~250-329 mg/dL)	5
	5.0-6.4 mmol/L (~190-249 mg/dL)	3
	4.0-4.9 mmol/L (~155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

Clinical Discussion: Praluent is a first-in-class PCSK9 inhibitor that has been shown to be clinically efficacious, lowering LDL-C by > 50 % compared to placebo in most clinical trials. No long-term outcomes data is available at this point, but ongoing studies are expected to conclude within the next few years. Praluent is administered as a 75 mg/mL SC injection every 2 weeks and appears to be well-tolerated. For patients who don't respond to therapy, it is recommended to increase the dose to 150 mg/mL every 2 weeks. These criteria were developed based on discussions with other ACHP plans.

Clinical Outcome: Dr. Perry Meadows made a motion to accept the recommendation as written. Jamie Dodson seconded the motion. None were opposed.

Proposed Financial Recommendations: Praluent should not be added to the GHP Family-

Healthy Connect formulary at this time. The following additional criteria should apply:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia

Quantity Limits: 2 mL per 28 days

Authorization Duration: Initial authorizations for PCSK9 Inhibitors will be approved for a period of 6 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to therapy

Reviewing providers should approve requests for Praluent by GPID.

Financial Discussion: No questions or comments.

Financial Outcome: Dr. Perry Meadows made a motion to accept the recommendations as written. Jamie Dodson seconded the motion. None were opposed.

Approved Recommendations: Praluent will not be added to the GHP Family-Healthy Connect formulary at this time

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia **AND** either:
    - Genetic testing to confirm a mutation in the LDL receptor gene **OR**
    - Medical record documentation of definite HeFH (score > 8) on the diagnostic criteria scoring system (Table 1) as defined by the ESC/EAS guidelines and the World Health Organization **AND**
- Prescription must be written by a cardiologist **AND**
- Medical record documentation of a baseline LDL at the start of PCSK9 therapy **AND**
- Medical record documentation that the patient is > 18 years of age **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to high-intensity statin therapy, including atorvastatin 40 mg or 80 mg or Crestor 20 mg or 40 mg, or the highest tolerable dose **AND**
- If a retrial of statins is not contraindicated (i.e., in patients with mild to moderate myalgia or myopathy or LFTs > 3x ULN that return to baseline upon discontinuation), medical record documentation of two retrials with lower doses or alternative statins is required **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**

- Medical record documentation an inability to achieve and maintain an LDL cholesterol level at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with a combination of medications, diet, and exercise.
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia

Quantity Limits: 2 mL per 28 days

Authorization Duration: Initial authorizations for PCSK9 Inhibitors will be approved for a period of 6 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to therapy

Reviewing providers should approve requests for Praluent by GPID.

Definitions:

- Therapeutic failure to statins and/or Zetia – inability to reach target LDL Goals (<100 mg/dL or <70 mg/dL based on patient risk) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
- Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).
- Intolerance to statins – increased LFTs, rhabdomyolysis, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms)
- Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

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Clinical history	Patient has premature CAD*	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tx	6
	Arcus cornealis below the age of 45 years	4
LDL-C	>8.5 mmol/L (more than ~330 mg/dL)	8
	6.5-8.4 mmol/L (~250-329 mg/dL)	5
	5.0-6.4 mmol/L (~190-249 mg/dL)	3
	4.0-4.9 mmol/L (~155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FORMULARY UPDATES:

SGLT-2 Inhibitors **Steven Kheloussi**

Steven Kheloussi provided a review of currently available SGLT-2 inhibitors to include:

Trade Name	Generic	Manufacturer
Invokana	canagliflozin	Janssen
Invokamet	canagliflozin/metformin	Janssen
Jardiance	empagliflozin	Boehringer Ingelheim Pharmaceuticals, Inc.
Glyxambi	empagliflozin/linagliptin	Boehringer Ingelheim Pharmaceuticals, Inc.
Farxiga	dapagliflozin	AstraZeneca
Xigduo XR	dapagliflozin/metformin ER	AstraZeneca

Clinical Discussion:

Safety

Each of the SGLT-2 inhibitors increases the incidence of genitourinary infections, increases LDL-C, and carries a risk of symptomatic hypotension. Few agent-specific adverse events also exist. With the exception of the major safety concern of a potentially increased risk of bladder cancer with Farxiga, these agents are very similar with regard to safety.

On May 15, 2015, the FDA issued a Drug Safety Communication regarding the risk of ketoacidosis with the use of SGLT-2 inhibitors. Though it is rare, it is a dangerous and costly adverse reaction. The warning did not single out a particular SGLT-2 inhibitor as more likely to cause ketoacidosis than the others.

Efficacy

AACE

The 2015 American Academy of Clinical Endocrinologists diabetes guidelines suggest metformin is the preferred first line oral antidiabetic in patients with an A1C < 7.5%. If patients cannot tolerate metformin, other appropriate first line agents (in order of preference) are GLP-1 agonists, SGLT-2 inhibitors, DPP-4 inhibitors, and alpha-glucosidase inhibitors. Thiazolidinediones (TZDs) and sulfonylureas are not preferred as monotherapy.

If a patient is still uncontrolled on metformin or another first line agent alone after 3 months or has an A1C > 7.5% at baseline, dual therapy with metformin or another "first-line agent" plus a second-line agent is recommended. Preferred second-line agents (in order of preference) are GLP-1 agonists, SGLT-2 inhibitors, DPP-4 inhibitors, TZDs, and insulin.

Preferred third-line agents (in order of preference) then are GLP-1 agonists, SGLT-2 inhibitors, TZDs, insulin, then DPP-4 inhibitors.

Ultimately, the AACE guideline recommends SGLT-2 inhibitors as second-line therapy only behind metformin and/or GLP-1 agonists.

ADA

The 2015 American Diabetes Association guidelines also suggest metformin as a first-line agent. However, this guideline does not take a preferential approach with any second-line agent, suggesting metformin plus any of the following is appropriate – a sulfonylurea, TZD, DPP-4

inhibitor, SGLT-2 inhibitor, GLP-1 agonist, or basal insulin.

Third-line therapy then consists of adding a third agent from any class, with the exception of combining a DPP-4 inhibitor or an SGLT-2 inhibitor with a GLP-1 agonist.

Financial Discussion

Drug	AWP/MAC per unit ($)	AWP/MAC per 28 day supply ($)
Invokana	$13.71	$383.88
Jardiance	$13.71	$383.88
Farxiga	$13.72	$384.16

Recommendations
Invokana and Jardiance are both reasonable options as second-line therapy for diabetes.

- For Jardiance, it is recommended that the current step therapy wording be updated to read:
    - Medical record documentation that Jardiance is being used in combination with (or therapeutic failure on, intolerance to, or contraindication to) metformin
    - Quantity limits of 1 tablet per day should apply.
- Invokana should be added to the GHP Family-Healthy Connect Formulary. It is recommended that the current prior authorization be changed to step therapy and the policy be updated to read:
    - Medical record documentation that Invokana is being used in combination with (or therapeutic failure on, intolerance to, or contraindication to) metformin.
    - Quantity limits of 1 tablet per day should apply.
- Invokamet should be moved to the GHP Family-Healthy Connect formulary. It is recommended that the current prior authorization be changed to step therapy and the policy be updated to read:
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to metformin.
    - Quantity limits of 2 tablets per day should still apply.
- Given the risk of bladder cancer with Farxiga and Xigduo XR, it is recommended that no changes be made to their nonformulary status. For these LOB, prior authorization criteria should be updated to read:
    - For Farxiga: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Invokana and Jardiance.
    - Xigduo XR should remain nonformulary and the prior authorization criteria and quantity limits should remain unchanged.

Discussion: No questions or comments.

Outcome: Kimberly Clark made a motion to accept the recommendations as written. Dr. Perry Meadows seconded the motion. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Inhaled Corticosteroids **Kimberly Clark**

Kimberly Clark provided a review of currently available inhaled corticosteroids to include:

Trade Name	Generic	Dosing Frequency	FDA Approved Ages	Manufacturer
Arnuity Ellipta	Fluticasone furoate	Once daily	> 12 years	GlaxoSmithKline
Flovent Diskus	Fluticasone propionate	Twice daily	> 4 years	GlaxoSmithKline
Flovent HFA	Fluticasone propionate	Twice daily	> 4 years	GlaxoSmithKline
Qvar	Beclomethasone	Twice daily	> 5 years	Teva
Pulmicort Flexhaler	Budesonide	Twice daily	> 6 years	AstraZeneca
Asmanex HFA	Mometasone	Twice daily	> 12 years	Merck Sharp & Dohme
Asmanex Twisthaler	Mometasone	Once or twice daily	> 4 years	Merck Sharp & Dohme

Clinical Discussion:

Safety

The overall incidence rate of adverse events is similar among ICSs. Taking the whole body of evidence into consideration, discontinuation rates because of adverse events do not differ significantly.

Efficacy

Overall, efficacy studies provide fair evidence that, at equipotent doses administered through comparable delivery devices, ICSs do not differ in their ability to control asthma symptoms and reduce the need for additional rescue medication.

Financial Discussion: no questions or comments

Recommendations

- The formulary status of the following products will not change:
  - Qvar – no-formulary
  - Pulmicort Flexhaler – Non-formulary
- The formulary status of the following products will be updated:
  - Asmanex HFA/Twisthaler – non-formulary
  - Arnuity Ellipta – Formulary
  - Flovent HFA/Diskus – Formulary with age restriction to those under the age of 12
- Authorizations will be entered to allow members currently utilizing Asmanex who are under the age of 12 to continue on therapy. Members 12 years of age and older will be sent a letter notifying them of the need to switch to Arnuity Ellipta.
- Flovent HFA/Diskus will remain on the formulary with an age block in place to limit therapy to those under the age of 12 years. Members 12 years of age and older will be sent a letter notifying them of the need to switch to Arnuity Ellipta.

Discussion: No questions or comments.

Outcome: Dr. Perry Meadows made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Finished meeting at 1:40 pm.

Future Scheduled Meetings

September 15, 2015 at 1:00 HCSRLL Conference room

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821.