P&T Committee Meeting Minutes
(GHP Family)
May 21, 2013

Please Note: The Geisinger Health Plan Pharmacy & Therapeutics Committee Meeting minutes and materials supplied are to be considered confidential and should not be shared or distributed to anyone outside of this committee.

Present:	**Absent:**
Bret Yarczower, MD, MBA, – Chair Ali Akram, Pharm.D. MBA Kristen Bender, Pharm.D. Fred Bloom, MD Holly Bones, Pharm.D. via phone Kimberly Clark, Pharm.D. Jamie Dodson, RPh Michelle Holt-Macey, Pharm.D. – via phone Steven Kheloussi, Pharm.D. – via phone Lisa Mazonkey, RPh Daniel McConnell, Pharm.D., RPh Jonas Pearson, MS, RPh David Rolston, MD – via phone William Seavey, Pharm.D. – via phone Richard Silbert, MD – via phone Leah Smith, Pharm.D. Michael Spishock, RPh Todd Sponenberg, Pharm.D., RPh Kevin Szczecina, RPh Lori Zaleski, RPh – via phone	Charles Baumgart, MD, MBA Beverly Blaisure, MD – excused Kristen DiOrio, Pharm.D. Dorothy Fisher, MD Phillip Krebs, R.EEG T. Peter Mikhail, Pharm.D., MBA, – Secretary Ray Roth, DO, MBA James Schuster, MD Steve Tracy, Pharm.D .Lori Zaleski, RPh Bethany Venit

Call To Order:
Bret Yarczower called the meeting to order at 1:00 p.m., Tuesday, May 21, 2013

Review and Approval of Minutes:
Bret Yarczower asked for a motion or approval to accept the March 19, 2013 minutes as presented.

Kimberly Clark made a motion to accept the recommendations as written. Jamie Dodson accepted the motion. None were opposed.

DRUG REVIEWS

NESINA, KAZANO, & OSENI – Kimberly Clark
(alopliptin, alogliptin/metformin, alogliptin/pioglitazone)

Kimberly Clark provided a review of Nesina, Kazano, and Oseni to the committee for consideration as pharmacy benefits. Nesina, Kazano, and Oseni are each indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. GHP Family Formulary alternatives include pioglitazone, metformin, metformin ER, Januvia, Janumet, Janumet XR, Kombiglyze XR, and Onglyza

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A. Proposed Clinical Recommendations: Nesina, Kazano, and Oseni appear to be safe and effective in patients with type 2 diabetes. However, they do not appear to have a unique role in therapy. Based on this information, it is recommended that Nesina, Kazano, and Oseni be added to the formulary requiring step therapy.

Clinical Discussion: FDA Approved Indications, Summary of Disease State, Pharmacology, Clinical Evidence of Safety and Efficacy, Dosing Schedule, Monitoring, Safety Profile, Patent Life, Distinct Features, Recommendations of National Agencies and Organizations, Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Jonas Pearson made a motion to accept the recommendations as written. Lisa Mazonkey accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Nesina, Kazano, and Oseni be added to the GHP Family formulary with step therapy. The following criteria should apply to exception requests:

NESINA:
- A diagnosis of type II diabetes mellitus **AND**
- Is being used with (or therapeutic failure on, intolerance to, or contraindication to) metformin

KAZANO:
- A diagnosis of type II diabetes mellitus **AND**
- Is being used with (or therapeutic failure on, intolerance to, or contraindication to) metformin

OSENI:
- A diagnosis of type II diabetes mellitus **AND**
- Is being used with (or therapeutic failure on, intolerance to, or contraindication to) metformin

Financial Discussion: No questions or comments.

Financial Outcome:
NESINA: Kevin Szczecina made a motion to accept the recommendations as written. Jonas Pearson accepted the motion. None were opposed.
KAZANO: Kevin Szczecina made a motion to accept the recommendations as written. Jonas Pearson accepted the motion. None we opposed.

OSENI: Kevin Szczecina made a motion to accept the recommendations as written. Jonas Pearson accepted the motion. None were opposed

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B. Approved Recommendations: Nesina, Kazano, and Oseni will be added to the GHP Family formulary. The following criteria will apply to exception requests:

NESINA:

- A diagnosis of type II diabetes mellitus **AND**
- Is being used with (or therapeutic failure on, intolerance to, or contraindication to) metformin

KAZANO:

- A diagnosis of type II diabetes mellitus **AND**
- Is being used with (or therapeutic failure on, intolerance to, or contraindication to) metformin

OSENI:

- A diagnosis of type II diabetes mellitus **AND**
- Is being used with (or therapeutic failure on, intolerance to, or contraindication to) metformin

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

KADCYLA (ado-trastuzumab emtansine) – Ali Akram

Ali Akram provided a review of Kadcyla to the committee for consideration as a medical benefit. Kadcyla is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: received prior therapy for metastatic disease OR developed disease recurrence during or within six months of completing adjuvant therapy. GHP Family pharmacy formulary alternatives are Tykerb and Xeloda.

A. Proposed Clinical Recommendations: It is recommended that Kadcyla be considered a Medical benefit for GHP Family. The following criteria should apply:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of adult patients with HER2-positive, metastatic breast cancer **AND**
- Medical record documentation of previous treatment with trastuzumab (Herceptin) and a taxane (paclitaxel or docetaxel), separately or in combination. Member must have either:
    - Received prior therapy for metastatic disease, or
    - Developed disease recurrence during or within six months of complete adjuvant

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Jonas Pearson made a motion to accept the recommendations as written. Lisa Mazonkey accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Kadcyla be considered a Medical Benefit with prior authorization criteria for GHP Family.

Financial Discussion: No questions or comments.

Financial Outcome: Jamie Dodson made a motion to accept the recommendations as written. Jonas Pearson accepted the motion. None were opposed.

B. Approved Recommendations: Kadcyla will be considered a medical benefit requiring prior authorization for GHP Family. The following criteria will apply:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of adult patients with HER2-positive, metastatic breast cancer **AND**
- Medical record documentation of previous treatment with trastuzumab (Herceptin) and a taxane (paclitaxel or docetaxel), separately or in combination. Member must have either:
    - Received prior therapy for metastatic disease, or
    - Developed disease recurrence during or within six months of complete adjuvant

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

ABILIFY MAINTENA (aripiprazole) – Kimberly Clark

Kimberly Clark provided a review of Abilify Maintena to the committee for consideration as a pharmacy benefit. Abilify Maintena is an atypical antipsychotic indicated for the treatment of schizophrenia.

A. Proposed Clinical Recommendations: Abilify Maintena will be considered a medical benefit for GHP Family members. It appears to be effective and relatively safe for use in schizophrenic patients who demonstrate poor adherence to oral therapy. To ensure appropriate utilization, it is recommended that the following prior authorization criteria apply to exception requests. The following prior authorization criteria should apply:

- Medical record documentation of schizophrenia **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of documented history of poor adherence to oral medication and documentation that patient education to improve adherence have been attempted

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. Dr. Silbert noted that Abilify Maintena has less storage issues than some other agents and requires less monitoring time after administration than some other agents. He also noted that it is hard to establish superiority to other atypical long acting injectable antipsychotics. No further questions or comments.

Clinical Outcome: Ali Akram made a motion to accept the recommendations. Kevin Szczecina accepted the motion. None were opposed.

Financial Recommendation: It is recommended that in addition to the criteria above, the following criteria apply:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Risperdal Consta, Zyprexa Relprevv, and Invega Sustenna

Financial Discussion: No questions or comments.

Financial Outcome: Jonas Pearson made a motion to accept the recommendations. Kevin Szczecina accepted the motion. None were opposed.

B. Approved Recommendations: Abilify Maintena will be moved to the Specialty Tier for 2014. The following prior authorization criteria will apply:

- Medical record documentation of schizophrenia **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of documented history of poor adherence to oral medication and documentation that patient education to improve adherence have been attempted **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Risperdal Consta, Zyprexa Relprevv, and Invega Sustenna.

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

JUXTAPID (lomitapide) – Leah Smith

Leah Smith provided a review of Juxtapid to the committee for consideration as a pharmacy benefit. Juxtapid is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C) total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). GHP Family formulary alternatives include atorvastatin, simvastatin and Zetia.

A. Proposed Clinical Recommendations: Recommend that Juxtapid be non-formulary.

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. Dr. Yarczower recommended that the prior authorization criteria be tabled until the committee could determine what a reasonable LDL goal would be to increase longevity and improve clinical outcomes for these patients and also until the competitor product, Kynamro, can be reviewed at an upcoming P&T meeting. No further questions or comments.

Clinical Outcome: The clinical decision was tabled until acceptable prior authorization criteria for Juxtapid can be determined.

Financial Recommendation: It is recommended that this medication not be added to the formulary.

Financial Discussion: No questions or comments.

Financial Outcome: Ali Akram made a motion to accept the recommendations as written. Kimberly Clark accepted the motion. None were opposed.

B. Approved Recommendations: Juxtapid will not be added to the GHP Family formulary. A final decision regarding prior authorization criteria will be decided once a reasonable LDL goal can be determined and once the competitor product, Kynamro, can be reviewed at an upcoming P&T meeting.

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

AUVI-Q (epinephrine) – Kimberly Clark

Kimberly Clark provided a review of Auvi-Q to the committee for consideration as a pharmacy benefit. Auvi-Q contains epinephrine, a non-selective alpha and beta-adrenergic receptor agonist, indicated in the emergency treatment of allergic reactions (Type 1) including anaphylaxis. GHP Family formulary alternatives include Epi-Pen.

A. Proposed Clinical Recommendations: It is recommended that Auvi-Q be added to the GHP Family formulary.

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Lisa Mazonkey made a motion to accept as written. Jonas Pearson accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Auvi-Q be added to the GHP Family formulary with a quantity limit of 2 auto-injectors (1 box) per fill.

Financial Discussion: No questions or comments.

Financial Outcome: Lisa Mazonkey made a motion to accept the recommendations as written. Jonas Pearson accepted the motion. None were opposed.

B. Approved Recommendations:
Auvi-Q will be added to the GHP Family formulary with a quantity limit of 2 auto-injectors (1 box) per fill.

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

POMALYST (pomalidomide) – Ali Akram

Ali Akram provided a review of Pomalyst to the committee for consideration as a pharmacy benefit. Pomalyst is a thalidomide analogue indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomine (Revlimid) and bortezomib (Velcade) and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified. Revlimid is a GHP Family formulary alternative.

A. Proposed Clinical Recommendations: Based on clinical data, it is recommended that Pomalyst be considered a pharmacy benefit and added to the GHP Family formulary with the following prior authorization criteria:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of multiple myeloma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies: bortezomib (Velcade) and lenalidomide (Revlimid)

Q/L: 21 tablets per 28 days
Treatment period will be defined as 3 months. Re-review will be every 3 months. Pomalyst will no longer be considered medically necessary if there is medical record documentation of disease progression.

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Jonas Pearson made a motion to accept as written. Jamie Dodson accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Pomalyst be added to the GHP Family formulary requiring prior authorization and a quantity limit.

Financial Discussion: No questions or comments.

Financial Outcome: Jonas Pearson made a motion to accept the recommendations as written. Dan McConnell accepted the motion. None were opposed.

B. Approved Recommendations: Pomalyst will be added to the GHP Family formulary with the following prior authorization criteria:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of multiple myeloma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies: bortezomib (Velcade) and lenalidomide (Revlimid)

Q/L: 21 tablets per 28 days
Treatment period will be defined as 3 months. Re-review will be every 3 months. Pomalyst will no longer be considered medically necessary if there is medical record documentation of disease progression.

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

VASCEPA (icosapent ethyl) – Kimberly Clark

Kimberly Clark provided a review of Vascepa to the committee for consideration as a pharmacy benefit. Vascepa is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. The effect of Vascepa on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined. GHP Family formulary alternatives include atorvastatin, fenofibrate, gemfibrozil, lovastatin, pravastatin, and simvastatin.

A. Proposed Clinical Recommendations: It is recommended that Vascepa not be added to the GHP Family formulary.

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Kevin Szczezina made a motion to accept the recommendations as written. Ali Akram
Pearson accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Vascepa not be added to the GHP Family formulary and have a quantity limit of 4 capsules per day.

Financial Discussion: No questions or comments.

Financial Outcome: Kevin Szczenia made a motion to accept the recommendations as written Dan McConnell accepted the motion. None were opposed.

B. Approved Recommendations: Vascepa will not be added to the GHP Family formulary and will have the following prior authorization criteria:

1. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to gemfibrozil and fenofibrate and 3 formulary statins **AND**
2. Medical record documentation of triglyceride (TG) levels $\geq$ 500 mg/dL

Quantity Limit: 4 tablets per day

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

ELIQUIS (apixaban) – Leah Smith

Leah Smith provided a review of Eliquis to the committee for consideration as a pharmacy benefit. Eliquis is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. GHP Family formulary alternatives include warfarin, Xarelto and Pradaxa.

A. Proposed Clinical Recommendations: It is recommended that Eliquis be made non-formulary on the GHP Family formulary.

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Jonas Pearson made a motion to accept the recommendations as written. Lisa Mazonkey accepted the motion. None were opposed.

Financial Recommendation: It was recommended that Eliquis be made non-formulary on the GHP Family formulary.

Financial Discussion: No questions or comments.

Financial Outcome: Fred Bloom made a motion to accept the recommendations as written. Jonas Pearson accepted the motion. None were opposed.

B. Approved Recommendations: Eliquis will be non-formulary on the GHP Family formulary.

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

JETREA (ocriplasmin) – Kimberly Clark

Kimberly Clark provided a review of Jetrea to the committee for consideration as a medical benefit. Jetrea is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion. There are no formulary alternatives available.

A. Proposed Clinical Recommendations: It is recommended that Jetrea be considered a medical benefit for GHP Family. In order to ensure appropriate utilization, the following criteria should apply to exception requests:

- Medical record documentation that Jetrea is being prescribed by a retinal specialist **AND**
- Medical record documentation of a diagnosis of symptomatic vitreomacular adhesion **AND**
- Medical record documentation of decreased visual acuity **AND**
- Medical record documentation of symptoms which may include, but are not limited to visual distortion, black spots, or floaters **AND**
- Medical record documentation the member has not previously been treated with ocriplasmin

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. The health plan does not currently require prior authorization on other intravitreal injection. The concern is that members won't get a necessary treatment in an appropriate time frame. Dr. Yarczower recommended that the prior authorization criteria be removed and that a retrospective process be utilized to ensure appropriate utilization No questions or comments.

Clinical Outcome: Jonas Pearson made a motion to accept the recommendations as amended. Dan McConnell accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Jetrea be considered a medical benefit. A limit of two fills per lifetime (one injection per eye) should be applied.

Financial Discussion: No questions or comments.

Financial Outcome: Dan McConnell made a motion to accept the recommendations as written. Kevin Szczecina accepted the motion. None were opposed.

B. Approved Recommendations: Jetrea will be covered as a medical benefit with no prior authorization required. A retrospective prior authorization will be in place utilizing the following criteria:

- Medical record documentation that Jetrea is being prescribed by a retinal specialist **AND**
- Medical record documentation of a diagnosis of symptomatic vitreomacular adhesion **AND**
- Medical record documentation of decreased visual acuity **AND**
- Medical record documentation of symptoms which may include, but are not limited to visual distortion, black spots, or floaters **AND**
- Medical record documentation the member has not previously been treated with ocriplasmin

A limit of two fills per lifetime (one injection per eye) will be applied.

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

ZORTRESS (everolimus) – Ali Akram

Ali Akram provided a review of Zortress to the committee for consideration as a pharmacy benefit. Zortress was approved by the FDA back in 2010 and is currently non-formulary. It received approval in February 2013 for use in liver transplant patients. Zortress is indicated for the prophylaxis of organ rejection in adult patients:

- Kidney transplant: at low-moderate immunologic risk. Use in combination with basiliximab (Simulect) induction, cyclosporine (reduced dose), and corticosteroids.
- Liver transplant: Administer no earlier than 30 days post-transplant. Use in combination with tacrolimus (reduced doses) and corticosteroids.
- Limitations of Use: Safety and efficacy has not been established in the following:
    - Kidney transplant patients at high immunologic risk
    - Recipients of transplanted organs other than kidney or liver
    - Pediatric patients (< 18 years)

GHP Family formulary alternatives include azathioprine, mycophenolate, Gengraf and Rapamune.

A. Proposed Clinical Recommendations: It is recommended that Zortress be added to the GHP Family formulary with the following prior authorization criteria:

- Member must have a documented kidney transplant **AND**
- Prescription ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Member is 18 years of age or older **AND**
- Zortress is being administered in combination with basiliximab (Simulect) induction and concurrently with reduced doses or cyclosporine and corticosteroids

OR

- Member must have a documented liver transplant **AND**
- Prescription ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Member is 18 years of age or older **AND**
- Zortress is being administered no earlier than 30 days post-transplant with low dose tacrolimus and corticosteroids

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Dan McConnell made a motion to accept the recommendations as written. Kevin Szczecina accepted the motion. None were opposed.

Financial Recommendation: It is recommended that Zortress be added to the GHP Family formulary with prior authorization criteria.

Financial Discussion: No questions or comments.

Financial Outcome: Jamie Dodson made a motion to accept the recommendations as written. Ali Akram accepted the motion. None were opposed.

B. Approved Recommendations: Zortress will be added to the GHP Family formulary. The following prior authorization will be applied:

- Member must have a documented kidney transplant **AND**
- Prescription ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Member is 18 years of age or older **AND**
- Zortress is being administered in combination with basiliximab (Simulect) induction and concurrently with reduced doses or cyclosporine and corticosteroids

OR

- Member must have a documented liver transplant **AND**
- Prescription ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Member is 18 years of age or older **AND**
- Zortress is being administered no earlier than 30 days post-transplant with low dose tacrolimus and corticosteroids

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

CLASS REVIEW

TRIPTAN CLASS REVIEW – Leah Smith

Leah Smith provided a class review of the triptan products to the committee. The review included MITRE (sumatriptan), Zooming (zolmitriptan), Amerge (naratriptan), Maxalt (rizatriptan), Axert (almotriptan), Frova (frovatriptan), Relpax (eletriptan), Treximet (sumatriptan and naproxen), Sumavel DosePro (sumatriptan), Alsuma (sumatriptan), and Zecuity (sumatriptan).

A. Proposed Clinical Recommendations: The following recommendations were made for the triptan class for GHP Family:

- Add generic Rizatriptan (tabs and MLT) to the formulary
- Change QL of all current formulary triptans to 16 tabs per 28 days.
    - For Injections and Nasal spray formulations, also use a 16 dose per 28 day limit.
    - QL exceptions would need to include the following criteria
        - Prescribed by Neurologist
        - The > 16 dose per month prescription is being used for a medically accepted indication, including, but not limited to cluster headaches, headache bridging and menstrual migraine.
        - The patient is not using concurrent chronic opioid or barbiturate therapy for migraine treatment

        - Medical record documentation of current use of prophylaxis therapy or therapeutic failure, contraindication, or intolerance to ALL of the following:
            - Beta blocker (metoprolol, propranolol, atenolol, nadolol, or timolol),
            - Topiramate,
            - Amitriptyline,
            - Divalproex or Sodium Valproate AND
            - Venlafaxine
        - If the QL exception is being made for headache bridging therapy only a onetime prior authorization override will be provided. Future need for a triptan headache bridge will require additional prior authorization.

Clinical Discussion: FDA Approved Indications, Pharmacology, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Safety Profile, Patent Life, Distinct Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. No questions or comments.

Clinical Outcome: Jamie Dodson made a motion to accept the recommendations as written. Ali Akram seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended to add rizatriptan tabs and MLT formulations to the GHP Family formulary with quantity limits as previously discussed.

Financial Discussion: No other comments or questions

Financial Outcome: Daniel McConnell made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

B. Approved Recommendations: The following addition and quantity limits will applied:

- Add generic Rizatriptan (tabs and MLT) to the formulary
- Change QL of all current formulary triptans to 16 tabs per 28 days.
    - For Injections and Nasal spray formulations, also use a 16 dose per 28 day limit.
    - QL exceptions would need to include the following criteria
        - Prescribed by Neurologist
        - The > 16 dose per month prescription is being used for a medically accepted indication, including, but not limited to cluster headaches, headache bridging and menstrual migraine.
        - The patient is not using concurrent chronic opioid or barbiturate therapy for migraine treatment
        - Medical record documentation of current use of prophylaxis therapy or therapeutic failure, contraindication, or intolerance to ALL of the following:
            - Beta blocker (metoprolol, propranolol, atenolol, nadolol, or timolol),
            - Topiramate,
            - Amitriptyline,
            - Divalproex or Sodium Valproate AND
            - Venlafaxine

- If the QL exception is being made for headache bridging therapy only a onetime prior authorization override will be provided. Future need for a triptan headache bridge will require additional prior authorization.

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

FAST FACTS

EDURANT (rilpivirine) – Kimberly Clark

Kimberly Clark provided a fast facts review of an expanded indication for Edurant. Edurant is a human immunodeficiency virus type 1 (HIV-1) specific, non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated:

- In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve adult patients with HIV-1 RNA less than or equal to 100,000 copies/mL.
- This indication is based on safety and efficacy analyses through 96 weeks from 2 randomized, double-blind, active controlled, Phase 3 trials in treatment-naïve subjects.
- The following points should be considered when initiating therapy with Edurant:
  - More Edurant treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA ≥ 50 copies/mL) compared to Edurant treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL.
  - Regardless of HIV-1 RNA at the start of therapy, more Edurant treated subjects with CD4+ cell count less than 200 cells/mm^3 at the start of therapy experienced virologic failure compared to subjects with CD4+ cell count greater than or equal to 200 cells/mm^3.
  - The observed virologic failure rate in Edurant treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz.
  - More subjects treated with Edurant developed tenofovir and lamivudine/emtricitabine associated resistance compared to efavirenz.
- Edurant is not recommended for patients less than 18 years of age.

Recommendations: Edurant is currently formulary for GHP Family.

Discussion: No formulary changes recommended. A quantity limit of one tablet per day will be added. No questions or comments.

Outcome: Dan McConnell made the motion to accept the recommendations as amended. Jamie Dodson accepted the motion. None were opposed.

BOTOX (onabotulinumtoxinA) – Ali Akram

Ali Akram provided a fast facts review of a new indication for Botox. Botox is now indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Recommendations: Botox is a medical benefit for GHP Family. It is recommended that the indication be added to the Botox medical benefit policy. The following prior authorization criteria will apply:

- Medical record documentation of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adult members **AND**
- Medical record documentation of at least 3 urinary urgency incontinence episodes and at least 24 micturitions in 3 days **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two oral anticholinergic medications therapies

Initial authorization: 100 units (20 injects of 5 units)
Future authorizations of 100 units each (20 injections of 5 units): Medical record documentation of:

- At least 12 weeks having passed since the prior treatment **AND**
- Post-void residual urine volume must have been less than 200 mL **AND**
- Member must have reported at least 2 urinary incontinence episodes over 3 days

Outcome: Kimberly Clark made the motion to accept the recommendations as written. Jamie Dodson accepted 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.

TAMIFLU (osteltamivir phosphate) – Kimberly Clark

Kimberly Clark provided a fast facts review of an expanded population for Tamiflu. Tamiflu is an influenza neuraminidase inhibitor, now indicated for the treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days.

Recommendations: Tamiflu is currently on the GHP Family formulary. There are no changes recommended at this time due to the expanded indication.

Discussion: It was recommended that the quantity limit of one fill per influenza season be increased to one fill per 6 month time frame. No further questions or comments.

Outcome: Jamie Dodson made the motion to accept the recommendation as amended with addition of a quantity limit of 1 fill every 6 months. Daniel McConnell accepted 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.

STIVARGA (regorafenib) – Ali Akram

Ali Akram provided a fast facts review of a new indication for Stivarga. Stivarga is now indicated for locally advances, unresectable or metastatic gastrointestinal stromal tumors (GIST) that have been previously treated with imatinib mesylate (Gleevec) and sunitinib malate (Sutent).

Recommendations: It is recommended that the indication for GIST be added to the existing Stivarga policy. The following criteria should apply:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to imatinib mesylate (Gleevec) and sunitinib malate (Sutent)

Discussion: No questions or comments.

Outcome: Jamie Dodson made the motion to accept the recommendations as written. Dan McConnell accepted 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.

EXJADE (deferasirox) – Kimberly Clark

Kimberly Clark provided a fast facts review of a new indication for Exjade. Exjade is a heavy metal chelator which is now indicated for the treatment of chronic iron overload in adults and children 10 years or older as a result of a genetic blood disorder called non-transfusion-dependent-thalassemia (NTDT). Exjade should be used in patients who have a liver iron concentration of at least 5 milligrams of iron per gram of dry liver tissue weight (mg Fe/g dw).

Recommendations: Exjade is currently non-formulary for GHP Family and the new indication was previously addressed in the Exjade policy. It is recommended that Exjade remain non-formulary.

Discussion: The need for medical record documentation of a serum ferritin level > 1000 mcg/L was added to the Transfusional –Dependent Thalassemia indication. **"**If approved, approval is for 3 months. To continue to be considered medically necessary there must be medical record documentation of a decreased serum ferritin level from baseline for overload caused by blood transfusions OR of a decreased LIC from baseline AND serum ferritin level < 300 mcg/ml for overload caused by non-transfusional dependent thalassemia syndromes" was also added to the policy**.** No questions or comments.

Outcome: Dan McConnell made the motion to accept the recommendations as written. Kevin Szczecina accepted 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.

LONG ACTING INJECTABLE ANTIPSYCHOTICS– Ali Akram

Ali Akram provided a Medical Benefit Policy update to the committee for the long acting injectable antipsychotics, Abilify Maintena, Zyprexa Relprevv, Invega Sustenna, and Risperdal Consta.

Recommendations: The following prior authorization criteria are recommended for both the Medical Benefit

Risperdal Consta

- Medical record documentation of bipolar disorder or Schizophrenia **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of documented history of poor adherence to oral medication and documentation that patients education to improve adherence have been attempted

Zyprexa Relprevv

- Medical record documentation of bipolar disorder or Schizophrenia **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of documented history of poor adherence to oral medication and documentation that patients education to improve adherence have been attempted **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Risperdal Consta

Invega Sustenna

- Medical record documentation of bipolar disorder or Schizophrenia **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of documented history of poor adherence to oral medication and documentation that patients education to improve adherence have been attempted **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Risperdal Consta and Zyprexa Relprevv

Abilify Maintena

- Medical record documentation of bipolar disorder or Schizophrenia **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of documented history of poor adherence to oral medication and documentation that patients education to improve adherence have been attempted **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Risperdal Consta, Zyprexa Relprevv, and Invega Sustenna.

Discussion: No questions or comments.

Outcome: Jamie Dodson made the motion to accept the recommendations as written. Kevin Szczecina accepted 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.

PRIOR AUTHORIZATION QUARTERLY CASE AUDIT REVIEW – Todd Sponenberg

Todd Sponenberg presented a report from the last Quarterly Case Audit Meeting held on May 20, 2013.

Discussion: No questions or comments

Outcome: No changes to the formulary were recommended based on the cases and medications reviewed.

Meeting ended at 4:20

Future meetings

July 16, 2013 at 1:00
September 17, 2013 at 1:00
November 12, 2013 at 1:00

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Bret Yarczower, MD
Chairperson

_____
Terri Kalejta
Recording Secretary