



**CABINET FOR HEALTH AND FAMILY SERVICES  
DEPARTMENT FOR MEDICAID SERVICES**

**Steven L. Beshear**  
Governor

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**Audrey Tayse Haynes**  
Secretary

**Lawrence Kissner**  
Commissioner

January 14, 2014

Pharmacy and Therapeutics Advisory Committee (PTAC):

The Department has reviewed the PTAC Recommendations resulting from the last meeting held on November 21, 2013. Outlined below are the results:

**Therapeutic Agents Class Review**

Accepted 22 of 22 Therapeutic Class PTAC Recommendations:

- Accepted 17 of 17 therapeutic class PTAC recommendations where **no difference** was noted from the Magellan Medicaid Administration (MMA) recommendations.
- Accepted 5 of 5 therapeutic class PTAC recommendations where a **difference** was noted from the MMA recommendations.

**New Products to Market Review**

Accepted 1 of 1 new product PTAC recommendations where **no difference** was noted from the MMA Recommendations.

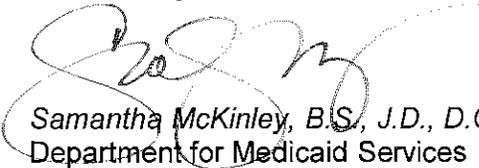
**Clinical Criteria Review**

Accepted 5 of 5 Clinical Criteria PTAC Recommendations; for the following products or classes: Itraconazole; and Hepatitis C: Interferon, Oral Protease Inhibitors, and Ribavirins

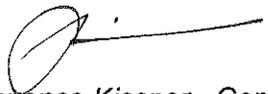
- Accepted 5 of 5 clinical criteria PTAC recommendations where **no difference** was noted from the MMA recommendations.

As always, we appreciate the efforts and insight of our PTAC members.

Kindest Regards,



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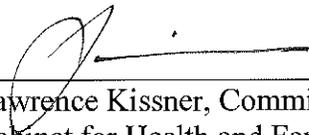
**FINAL DETERMINATION OF THE COMMISSIONER OF THE  
DEPARTMENT FOR MEDICAID SERVICES OF THE  
KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES  
ACCEPTING THE RECOMMENDATION  
OF THE PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE**

Pursuant to KRS 205.564(9) and 907 KAR 1:019, Section 8, after reviewing the recommendations of the Pharmacy and Therapeutics Advisory Committee ("Committee") made as a result of its discussions and meeting conducted on November 21, 2013, in Frankfort, Kentucky, and in consultation with the Department for Medicaid Services and any exceptions filed thereto in accordance with the provisions of 907 KAR 1:019:

I hereby **ACCEPT** and **ADOPT** the Committee's November 21, 2013, recommendations in full, which are attached hereto.

This determination is final and appealable.

**SO ORDERED** this the 28<sup>th</sup> day of January, 2013.

  
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Lawrence Kissner, Commissioner,  
Cabinet for Health and Family Services,  
Department for Medicaid Services

**Commissioner for the Department for Medicaid Services  
Selections for Preferred Products**

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for the Department for Medicaid Services based on the November 21, 2013 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

<b>Description of Recommendation</b>	<b>Final Decision (s)</b>
<p><b><u>New Products to Market: Gilotrif™</u></b> Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Gilotrif™ for a diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, which have been detected by an FDA-approved test.</p>	<p>Gilotrif™ will be added as preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Gilotrif™ will only be approved for a diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, which have been detected by an FDA-approved test.</p>
<p><b><u>Lipotropics, Statins</u></b> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue current quantity limits on agents in the class. 4. For any new chemical entity in the Lipotropics, Statins class, require a PA until reviewed by the P&amp;T Advisory Committee.</p>	<p>Selected Preferred Agent (s) Lescol XL® lovastatin pravastatin</p> <p>Non Preferred Agent (s) Advicor™ Altoprev® Lescol® Mevacor® Pravachol®</p>
<p><b><u>Bile Acid Sequestrants</u></b> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least cholestyramine should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Bile Acid Sequestrants class, require a PA until reviewed by the P&amp;T Advisory Committee.</p>	<p>Selected Preferred Agent (s) cholestyramine cholestyramine light</p> <p>Non Preferred Agent (s) Colestid® colestipol WelChol®</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Beta Blockers</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation. At least two non-selective beta blockers, at least one with ISA, should be preferred on the PDL. At least two cardioselective beta blockers should be preferred on the PDL. Included among the preferred products should be metoprolol succinate, metoprolol tartrate, bisoprolol, and a short-acting and a long-acting propranolol product.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Beta Blockers class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>atenolol  bisoprolol  metoprolol tartrate  pindolol  propranolol  propranolol LA  Toprol XL®</p> <p>Non Preferred Agent (s)</p> <p>acebutolol  betaxolol  Bystolic™  Corgard®  Inderal®  Innopran XL®  Kerlone®  Levatol®  Lopressor®  metoprolol succinate ER  nadolol  Sectral®  Tenormin®  timolol  Zebeta®</p>
<p><b><u>Beta Blocker + Diuretic</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least three combination products, one of which is atenolol/chlorthalidone, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Beta Blocker + Diuretic class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>atenolol / chlorthalidone  bisoprolol / HCTZ  propranolol / HCTZ</p> <p>Non Preferred Agent (s)</p> <p>Corzide®  Dutoprol™  Lopressor® HCT  metoprolol tartrate / HCTZ  nadolol / bendroflumethiazide  Tenoretic®  Ziac®</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Calcium Channel Blockers (DHP)</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities, one of which should be amlodipine, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Calcium Channel Blocker (DHP) class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>amlodipine felodipine ER nifedipine ER/SA/SR</p> <p>Non Preferred Agent (s)</p> <p>Adalat CC<sup>®</sup> Afeditab<sup>™</sup> CR Cardene<sup>®</sup> Cardene ER<sup>®</sup> isradipine nicardipine Nifediac CC<sup>®</sup> Nifedical XL<sup>®</sup> nifedipine nimodipine nisoldipine ER Norvasc<sup>®</sup> Nymalize<sup>®</sup> Plendil<sup>®</sup> Procardia<sup>®</sup> Procardia XL<sup>®</sup> Sular<sup>®</sup></p>
<p><b><u>Ophthalmic Beta Blockers</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Ophthalmic Beta Blockers class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>Betimol<sup>®</sup> levobunolol timolol maleate</p> <p>Non Preferred Agent (s)</p> <p>Betagan<sup>®</sup> betaxolol Betoptic S<sup>®</sup> carteolol Istalol<sup>®</sup> metipranolol Optipranolol<sup>®</sup> Timoptic<sup>®</sup> Timoptic XE<sup>®</sup></p>

Description of Recommendation	Final Decision (s)
<p><b><u>Long-Acting Beta<sub>2</sub> Adrenergic Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity available in a metered dose inhaler should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. Continue quantity limits on agents in this class.</li> <li>4. For any new chemical entity in the Long-Acting Beta<sub>2</sub> Adrenergic Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>Foradil<sup>®</sup> Aerolizer<sup>®</sup></p> <p>Non Preferred Agent (s)</p> <p>Arcapta<sup>™</sup> Neohaler<sup>™</sup></p> <p>Brovana<sup>®</sup></p> <p>Perforomist<sup>™</sup></p> <p>Serevent<sup>®</sup> Diskus</p>
<p><b><u>Hypoglycemics, Metformins</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least a short-acting and a long-acting metformin product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Hypoglycemics, Metformins class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>glyburide/metformin</p> <p>metformin</p> <p>metformin XR</p> <p>Non Preferred Agent (s)</p> <p>Fortamet<sup>™</sup></p> <p>glipizide/metformin</p> <p>Glucophage<sup>®</sup></p> <p>Glucophage XR<sup>®</sup></p> <p>Glucovance<sup>®</sup></p> <p>Glumetza<sup>™</sup></p> <p>Metaglip<sup>™</sup></p> <p>Riomet<sup>™</sup></p>

Description of Recommendation	Final Decision (s)
<p><b><u>Bone Resorption Suppression and Related Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least alendronate, calcitonin-salmon and raloxifene should be preferred on the PDL. Additionally, at least one bisphosphonate with a once-weekly dosing formulation should be preferred on the PDL</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Bone Resorption Suppression and Related Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>alendronate Evista® Fortical®</p> <p>Non Preferred Agent (s)</p> <p>Actonel® Actonel with Calcium® Atelvia™ Binosto® Boniva® calcitonin-salmon Didronel® etidronate Forteo™ Fosamax® Fosamax Plus D™ ibandronate Miacalcin® Prolia™ Reclast® Skelid® zoledronic acid</p>
<p><b><u>H. pylori Treatment</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent containing a Proton Pump Inhibitor (PPI), clarithromycin and either amoxicillin or metronidazole should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. Agents in this class should have quantity limits based on the FDA-approved maximum dose.</li> <li>4. For any new chemical entity in the <i>H. pylori</i> Treatment class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>Helidac® Prevpac® Pylera®</p> <p>Non Preferred Agent (s)</p> <p>lansoprazole, amoxicillin, clarithromycin Omeclamox-Pak™</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Oral Antifungals</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least fluconazole, griseofulvin, nystatin and terbinafine should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Oral Antifungal class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>clotrimazole  fluconazole  flucytosine  griseofulvin suspension  Gris-PEG<sup>®</sup>  Noxafil<sup>®</sup>  nystatin  terbinafine  voriconazole</p> <p>Non Preferred Agent (s)</p> <p>Ancobon<sup>®</sup>  Diflucan<sup>®</sup>  griesofulvin microsized  griesofulvin ultramicrosized  itraconazole  ketoconazole  Lamisil<sup>®</sup>  Lamisil<sup>®</sup> Granules  Mycelex Troche<sup>®</sup>  Nizoral<sup>®</sup>  nystatin  Onmel<sup>™</sup>  Oravig<sup>™</sup>  Sporanox<sup>®</sup>  Terbinex<sup>™</sup>  Vfend<sup>®</sup></p>

Description of Recommendation	Final Decision (s)
<p><b><u>Itraconazole Clinical Criteria</u></b>  Diagnoses to approve itraconazole:</p> <ul style="list-style-type: none"> <li>• Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot): <ul style="list-style-type: none"> <li>○ If the patient has NOT had a therapeutic failure on at least one topical antifungal medication, approve after trial and failure of a topical antifungal medication.</li> <li>○ If the patient has had a failure on at least one topical antifungal medication, approve: itraconazole capsules for once daily dosing for a 4-week continuous course of therapy.</li> </ul> </li> <li>• Patient can receive itraconazole automatically if diagnosis is Tinea Capitis for up to 4 weeks</li> <li>• Onychomycosis (fungal infection of the fingernails or toenails): For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO for retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment: <ul style="list-style-type: none"> <li>○ Fingernail Infection: Approve: itraconazole capsules for twice daily dosing for an 8-week continuous course of therapy.</li> <li>○ Toenail Infection: Approve: itraconazole capsules for once daily dosing for a 12-week continuous course of therapy.</li> </ul> </li> <li>• For the treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.</li> </ul>	<p>Itraconazole will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot): <ul style="list-style-type: none"> <li>○ If the patient has NOT had a therapeutic failure on at least one topical antifungal medication, approve after trial and failure of a topical antifungal medication.</li> <li>○ If the patient has had a failure on at least one topical antifungal medication, approve: itraconazole capsules for once daily dosing for a 4-week continuous course of therapy.</li> </ul> </li> <li>• Patient can receive itraconazole automatically if diagnosis is Tinea Capitis for up to 4 weeks</li> <li>• Onychomycosis (fungal infection of the fingernails or toenails): For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO for retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment: <ul style="list-style-type: none"> <li>○ Fingernail Infection: Approve: itraconazole capsules for twice daily dosing for an 8-week continuous course of therapy.</li> <li>○ Toenail Infection: Approve: itraconazole capsules for once daily dosing for a 12-week continuous course of therapy.</li> </ul> </li> <li>• For the treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.</li> </ul>

Description of Recommendation	Final Decision (s)
<p><b><u>Antivirals, Herpes</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least acyclovir and either valacyclovir or famciclovir should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Antivirals, Herpes class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>acyclovir famciclovir Valtrex®</p> <p>Non Preferred Agent (s)</p> <p>Famvir® valacyclovir Zovirax®</p>
<p><b><u>Antivirals, Flu</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least amantadine, oseltamivir, and zanamivir should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. DMS to consider CDC recommendation updates regarding antiviral therapy for the treatment of influenza. The Medical Director, with Commissioner approval, may make changes to the PDL listing based on the CDC recommendations until this class can be considered at the next scheduled review.</li> <li>4. For any new chemical entity in the Antivirals, Flu class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>amantadine syrup, tablets Relenza® rimantadine Tamiflu®</p> <p>Non Preferred Agent (s)</p> <p>amantadine capsules Flumadine® Symmetrel®</p>
<p><b><u>Sulfonamides, Folate Antagonists</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least trimethoprim/sulfamethoxazole should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Sulfonamides, Folate Antagonist class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>trimethoprim trimethoprim/sulfamethoxazole</p> <p>Non Preferred Agent (s)</p> <p>Bactrim® Bactrim DS® Primsol® sulfadiazine Septra DS®</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Hepatitis B Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least entecavir and lamivudine should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Hepatitis B Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>Baraclude™            Epivir HBV®            Hepsera®            Tyzeka®</p> <p>Non Preferred Agent (s)</p> <p>adefovir dipivoxil</p>
<p><b><u>Hepatitis C: Interferons</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred.</li> <li>3. PDL selected agents will apply for any new courses of therapy only.</li> <li>4. Place clinical prior authorization around the entire class to ensure appropriate utilization.</li> <li>5. Continue current quantity limits based on maximum approved dose.</li> <li>6. For any new chemical entity in the Hepatitis C: Interferons class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>PEGASYS® ProClick            PEGASYS® syringe</p> <p>Non Preferred Agent (s)</p> <p>Infergen®            PEGASYS® vial            PEGIntron™            PEGIntron™ Redipen®</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Hepatitis C Interferon Clinical Criteria</u></b></p> <p><b><u>Treatment Naive Patients:</u></b>            After the initial 18 weeks of therapy, interferons will be approved for a diagnosis of Hepatitis C if there is an Early Virologic Response. Early Virologic Response will be defined as either undetectable HCV RNA (&lt;50 IU/mL) or at least a 2 logarithmic drop in HCV RNA levels from baseline at treatment week 12.            Limitations on length of therapy is based on product and specific diagnosis:</p> <ul style="list-style-type: none"> <li>• Interferon alfacon-1               <ul style="list-style-type: none"> <li>○ INF naïve – 24 weeks total therapy</li> <li>○ INF relapse – 48 weeks total therapy</li> </ul> </li> <li>• Peginterferon alfa-2a OR 2b               <ul style="list-style-type: none"> <li>○ Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy</li> <li>○ Genotype 2, 3 – 24 weeks total therapy</li> </ul> </li> </ul> <p><b><u>Previously Treated or Relapsed Patients:</u></b>            Interferon therapy will only be approved in patients who have previously been treated if:</p> <ul style="list-style-type: none"> <li>• An Early Virologic Response was determined during the previous treatment course; OR</li> <li>• Patient was a partial or null responder to treatment with dual therapy consisting of interferon and ribavirin and               <ul style="list-style-type: none"> <li>○ Patient has diagnosis of genotype 1 Hepatitis C; and</li> <li>○ The prescriber feels that triple therapy may solicit a response.</li> </ul> </li> </ul> <p>Limitations on length of therapy are based on product and specific diagnosis:</p> <ul style="list-style-type: none"> <li>• Interferon alfacon-1               <ul style="list-style-type: none"> <li>○ INF naïve – 24 weeks total therapy</li> <li>○ INF relapse – 48 weeks total therapy</li> </ul> </li> <li>• Peginterferon alfa-2a OR 2b               <ul style="list-style-type: none"> <li>○ Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy</li> <li>○ Genotype 2, 3 – 24 weeks total therapy</li> </ul> </li> </ul>	<p><b><u>Treatment Naive Patients:</u></b>            After the initial 18 weeks of therapy, interferons will be approved for a diagnosis of Hepatitis C if there is an Early Virologic Response. Early Virologic Response will be defined as either undetectable HCV RNA (&lt;50 IU/mL) or at least a 2 logarithmic drop in HCV RNA levels from baseline at treatment week 12.            Limitations on length of therapy is based on product and specific diagnosis:</p> <ul style="list-style-type: none"> <li>• Interferon alfacon-1               <ul style="list-style-type: none"> <li>○ INF naïve – 24 weeks total therapy</li> <li>○ INF relapse – 48 weeks total therapy</li> </ul> </li> <li>• Peginterferon alfa-2a OR 2b               <ul style="list-style-type: none"> <li>○ Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy</li> <li>○ Genotype 2, 3 – 24 weeks total therapy</li> </ul> </li> </ul> <p><b><u>Previously Treated or Relapsed Patients:</u></b>            Interferon therapy will only be approved in patients who have previously been treated if:</p> <ul style="list-style-type: none"> <li>• An Early Virologic Response was determined during the previous treatment course; OR</li> <li>• Patient was a partial or null responder to treatment with dual therapy consisting of interferon and ribavirin and               <ul style="list-style-type: none"> <li>○ Patient has diagnosis of genotype 1 Hepatitis C; and</li> <li>○ The prescriber feels that triple therapy may solicit a response.</li> </ul> </li> </ul> <p>Limitations on length of therapy are based on product and specific diagnosis:</p> <ul style="list-style-type: none"> <li>• Interferon alfacon-1               <ul style="list-style-type: none"> <li>○ INF naïve – 24 weeks total therapy</li> <li>○ INF relapse – 48 weeks total therapy</li> </ul> </li> <li>• Peginterferon alfa-2a OR 2b               <ul style="list-style-type: none"> <li>○ Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy</li> <li>○ Genotype 2, 3 – 24 weeks total therapy</li> </ul> </li> </ul>

Description of Recommendation	Final Decision (s)
<p><b>Hepatitis C: Oral Protease Inhibitors</b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred.</li> <li>3. PDL selected agents will apply for any new courses of therapy only.</li> <li>4. Place clinical prior authorization around the entire class to ensure appropriate utilization.</li> <li>5. Continue quantity and duration limitations based on approved maximum dose and duration.</li> <li>6. For any new chemical entity in the Hepatitis C: Oral Protease Inhibitors class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>Incivek™ Victrelis™</p> <p>Non Preferred Agent (s)</p> <p>N/A</p>
<p><b>Hepatitis C: Oral Protease Inhibitors Clinical Criteria</b></p> <p>Boceprevir (Victrelis™) will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection after the patient has received 4 weeks of ribavirin and peginterferon therapy if the patient is receiving concurrent therapy with ribavirin and peginterferon.</p> <p>Telaprevir (Incivek™) will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon.</p> <p>Quantity and Duration Limits:</p> <ul style="list-style-type: none"> <li>• Incivek™: 6 per day; 1 course of oral protease inhibitor therapy per lifetime</li> <li>• Victrelis™: 12 per day; 1 course of oral protease inhibitor therapy per lifetime</li> </ul>	<p>Boceprevir (Victrelis™) will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection after the patient has received 4 weeks of ribavirin and peginterferon therapy if the patient is receiving concurrent therapy with ribavirin and peginterferon.</p> <p>Telaprevir (Incivek™) will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon.</p> <p>Quantity and Duration Limits:</p> <ul style="list-style-type: none"> <li>• Incivek™: 6 per day; 1 course of oral protease inhibitor therapy per lifetime</li> <li>• Victrelis™: 12 per day; 1 course of oral protease inhibitor therapy per lifetime</li> </ul>
<p><b>Hepatitis C: Ribavirins</b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least ribavirin should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred.</li> <li>3. Place clinical prior authorization around the entire class of ribavirins to ensure appropriate utilization.</li> <li>4. For any new chemical entity in the Hepatitis C: Ribavirins class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>ribavirin</p> <p>Non Preferred Agent (s)</p> <p>Copegus™ Rebetol® Ribasphere™ Ribasphere Ribapack™</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Hepatitis C: Ribavirins Clinical Criteria</u></b>  Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.</p>	Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.
<p><b><u>Progestins for Cachexia</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity must be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. For any new chemical entity in the Progestins for Cachexia class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)  megestrol acetate</p> <p>Non Preferred Agent (s)  Megace<sup>®</sup>  Megace ES<sup>®</sup></p>
<p><b><u>Pancreatic Enzymes</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one pancreatic enzyme product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Pancreatic Enzyme class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)  Creon<sup>®</sup>  pancrelipase  Zenpep<sup>®</sup></p> <p>Non Preferred Agent (s)  Pancreaze<sup>™</sup>  Pertzye<sup>™</sup>  Ultresa<sup>™</sup>  Viokace<sup>™</sup></p>
<p><b><u>Topical Immunomodulators</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Immunomodulators, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)  Elidel<sup>®</sup></p> <p>Non Preferred Agent (s)  Protopic<sup>®</sup></p>

Description of Recommendation	Final Decision (s)
<p><b><u>Immunosuppressants</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least five unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. DMS to allow continuation of therapy if there is a paid claim in the past 90 days.</li> <li>4. For any new chemical entity in the Immunosuppressants class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>Selected Preferred Agent (s)</p> <p>azathioprine  cyclosporine  cyclosporine modified  mycophenolate mofetil  Myfortic<sup>®</sup>  Rapamune<sup>®</sup>  tacrolimus</p> <p>Non Preferred Agent (s)</p> <p>Astagraf XL<sup>™</sup>  Azasan<sup>®</sup>  CellCept<sup>®</sup>  Gengraf<sup>®</sup>  Hecoria<sup>®</sup>  Imuran<sup>®</sup>  Neoral<sup>®</sup>  Prograf<sup>®</sup>  Sandimmune<sup>®</sup>  Zortress<sup>®</sup></p>