Secretary for Health and Family Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Secretary for Health and Family Services based on the July 21, 2011 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
New Products to Market: vandetanib Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.	Vandetanib will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.
New Products to Market: Viibryd® Place this product preferred in the PDL class titled Antidepressants: SSRIs; however, only approve Viibryd® after trial and failure of one SSRI.	Viibryd® will be placed preferred in the PDL class titled Antidepressants: SSRIs; however, Viibryd® will only be approved after trial and failure of one SSRI.
New Products to Market: Zytiga™ Place this product preferred in the PDL class titled Oral Oncology Agents; however, only approve in combination with prednisone for a diagnosis of metastatic castration-resistant prostate cancer (CRPC) after: • A trial of chemotherapy with docetaxel or mitoxantrone; OR • If the patient has a poor performance status.	Zytiga™ will be place preferred in the PDL class titled Oral Oncology Agents; however, it will only be approve in combination with prednisone for a diagnosis of metastatic castration-resistant prostate cancer (CRPC) after: • A trial of chemotherapy with docetaxel or mitoxantrone; OR • If the patient has a poor performance status.
New Products to Market: Horizant® Horizant® should be approved for a diagnosis of restless legs syndrome (RLS) after trail and failure of ONE of the following: o Levodopa/carbidopa, OR o Pramipexole, OR o Ropinirole.	Horizant® will be approved for a diagnosis of restless legs syndrome (RLS) after trail and failure of ONE of the following: o Levodopa/carbidopa, OR o Pramipexole, OR o Ropinirole.

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New Products to Market: Victrelis™ Victrelis™ should 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 they are receiving concurrent therapy with ribavirin and peginterferon. Victrelis™ should have a quantity limit of 12 capsules per day and be limited to one course of therapy per lifetime. Durations of therapy should be based on the following: a. Cirrhosis or previous treatment with peginterferon / ribavirin with documented lack of achievement of > 2 log reduction at week 12 with previous treatment: i. Approve for 14 weeks ii. After 14 weeks of therapy: 1. If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks 2. If HCV-RNA results at week 24 of therapy are undetectable, approve for an additional 18 weeks (44 weeks total therapy) 3. If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin). b. If none of above in a: i. Approve for 14 weeks ii. If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks iii. After 26 weeks, continuation of therapy should be approved based on the following: 1. Treatment naïve patients: a. If HCV-RNA results at week 8 and 24 are both undetectable – 2 more weeks then discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin) – total duration of Victrelis™ therapy = 28 weeks b. If HCV-RNA results at week 8 are detectable and week 24 are undetectable – 10 more weeks – total duration of Victrelis™ therapy = 36 weeks c. If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ ribavirin). 2. Previously treated or relapsed patients: a. If HCV-RNA results at week 8 and 24 are both undetectable – 10 more weeks (then	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 they are receiving concurrent therapy with ribavirin and peginterferon. Victrelis™ should have a quantity limit of 12 capsules per day and be limited to one course of therapy per lifetime. Durations of therapy will be based on the following: c. Cirrhosis or previous treatment with peginterferon / ribavirin with documented lack of achievement of > 2 log reduction at week 12 with previous treatment: i. Approve for 14 weeks ii. After 14 weeks of therapy: 1. If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks 2. If HCV-RNA results at week 24 of therapy are undetectable, approve for an additional 18 weeks (44 weeks total therapy) 3. If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin). d. If none of above in a: i. Approve for 14 weeks ii. If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks iii. After 26 weeks, continuation of therapy should be approved based on the following: 3. Treatment naïve patients: a. If HCV-RNA results at week 8 and 24 are both undetectable – 2 more weeks then discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin) – total duration of Victrelis™ therapy = 28 weeks b. If HCV-RNA results at week 8 are detectable and week 24 are undetectable – 10 more weeks – total duration of Victrelis™ therapy = 36 weeks

discontinue all 3) – total duration of Victrelis™ therapy = 36 weeks b. If HCV-RNA results at week 8 are detectable and week 24 results are undetectable 10 more weeks – total duration of Victrelis™ therapy = 36 weeks c. If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin).	c. If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ ribavirin). 4. Previously treated or relapsed patients: a. If HCV-RNA results at week 8 and 24 are both undetectable – 10 more weeks (then discontinue all 3) – total duration of Victrelis™ therapy = 36 weeks b. If HCV-RNA results at week 8 are detectable and week 24 results are undetectable 10 more weeks – total duration of Victrelis™ therapy = 36 weeks c. If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin).
New Products to Market: Incivek™ Incivek™ should be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon. Incivek™ should have a quantity limit of 6 tablets per day for a total duration of 12 weeks and be limited to one course of therapy per lifetime.	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. Incivek™ will have a quantity limit of 6 tablets per day for a total duration of 12 weeks and be limited to one course of therapy per lifetime.
New Products to Market: Sylatron™ Allow the use of Sylatron™ for a diagnosis of melanoma only.	Sylatron™ will be approved for a diagnosis of melanoma only.
New Products to Market: Tradjenta™ Place this product non preferred with similar quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors, unless cost parity to preferred DPP-4 Inhibitors.	Tradjenta™ will be placed non preferred with similar quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Daliresp™ Place this product preferred with similar quantity limits in the PDL class titled Anticholinergics, Inhaled; however, only approve after trial and failure of an inhaled anticholinergic or long-acting bronchodilator.	Daliresp™ will be placed preferred with similar quantity limits in the PDL class titled Anticholinergics, Inhaled; however, it will only be approve after trial and failure of an inhaled anticholinergic or long-acting bronchodilator.
New Products to Market: Natroba™ Place this product non preferred in the PDL class titled Topical Antiparasitics.	Natroba™ will be placed non preferred in the PDL class titled Topical Antiparasitics.

Description of Recommendation	Final Decision (s)
5-ASA Derivatives, Rectal Preparations 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity should be preferred. Both suppositories and enemas should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the 5-ASA Derivatives, Topical Preparations class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Canasa® mesalamine enemas sfRowasa® **Non Preferred** Agent (s) Rowasa®
5-ASA Derivatives, Oral Preparations 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities, one of which should be oral mesalamine, should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the 5-ASA Derivatives, Oral Preparations class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Apriso™ Asacol® balsalazide sulfasalazine sulfasalazine EC **Non Preferred** Agent (s) Asacol® HD Azulfidine® Azulfidine EN-tabs® Dipentum® Lialda™ Pentasa®
Anti-Migraine: 5-HT1 Receptor Agonists 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. Additionally, at least one non-oral dosage form should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Agents in this class should have quantity limits based on the FDA-approved maximum dose and duration. 4. As part of quantity limit override criteria, patients should be on concurrent migraine prophylaxis medication (beta blocker, tricyclic antidepressant, calcium channel blocker, etc.) at a therapeutic dose. 5. For any new chemical entity in the Anti-Migraine: 5-HT1 Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) sumatriptan **Non Preferred** Agent (s) Amerge® Axert® Cambia™ Frova™ Imitrex® Maxalt® naratriptan Relpax™ Sumavel™ Dosepro™ Treximet™ Zomig®

Description of Recommendation	Final Decision (s)
Hematopoietic Agents 1. DMS to select preferred agent (s) based upon economic evaluation. 2. All hematopoietic agents should require Prior Authorization. 3. For any agent not selected as preferred, DMS should allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Hematopoietic Agents class, require a PA until reviewed by the PTAC.	Selected **Preferred** Agent (s) Aranesp® Epogen® Procrit® **Non Preferred** Agent (s) N/A
Hematopoietic Agents Clinical Criteria Erythropoiesis stimulating agents should be approved for recipients meeting one of the following criteria: • The patient has a hemoglobin of less than 12 g/dL AND one of the following diagnoses: o Anemia associated with chronic renal failure OR anemia associated with kidney transplantation; OR o Treatment of chemotherapy induced anemia for non-myeloid malignancies; OR o Drug-induced anemia (examples, not all inclusive: Retrovir® or Combivir® or ribavirin); OR o Autologous blood donations by patients scheduled to undergo nonvascular surgery.	Erythropoiesis stimulating agents will be approved for recipients meeting one of the following criteria: • The patient has a hemoglobin of less than 12 g/dL AND one of the following diagnoses: o Anemia associated with chronic renal failure OR anemia associated with kidney transplantation; OR o Treatment of chemotherapy induced anemia for non-myeloid malignancies; OR o Drug-induced anemia (examples, not all inclusive: Retrovir® or Combivir® or ribavirin); OR o Autologous blood donations by patients scheduled to undergo nonvascular surgery.
Multiple Sclerosis Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least glatiramer, one interferon β-1b and one interferon β-1a product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Place quantity limits on these products based on maximum recommended dose. 4. For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Avonex® Betaseron® Copaxone® Rebif® **Non Preferred** Agent (s) Ampyra™ Extavia® Gilenya™

Description of Recommendation	Final Decision (s)
Ampyra™ Clinical Criteria After 12 weeks of therapy (84 days), Ampyra™ therapy will be allowed to continue if the diagnosis is multiple sclerosis and Ampyra™ has shown clinical efficacy.	After 12 weeks of therapy (84 days), Ampyra™ therapy will be allowed to continue if the diagnosis is multiple sclerosis and Ampyra™ has shown clinical efficacy.
Oral Antiemetics: Anticholinergics 1. DMS to select preferred agent (s) based on economic evaluation; however at least three unique chemical entities should be preferred. Promethazine and prochlorperazine should be among the preferred agents. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Oral Anti-Emetics: Anticholinergics class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) meclizine prochlorperazine promethazine trimethobenzamide **Non Preferred** Agent (s) Antivert® Phenergan® Tigan® Univert®
Oral Antiemetics: 5-HT_3 Antagonists 1. DMS to select preferred agent (s) based on economic evaluation; however at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Quantity limits should be removed from all oral dosages forms in this class. 4. For any new chemical entity in the Oral Anti-Emetics: 5-HT_3 Antagonists, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) ondansetron **Non Preferred** Agent (s) Aloxi® Anzemet® granisetron Granisol™ Kytril® Sancuso® Zofran® Zuplenz®
Sancuso® Clinical Criteria Sancuso® should be approved if the patient is currently undergoing cancer chemotherapy and one of the following is true: o The provider wishes to use this product to avoid the need for IV anti-emetics; OR o There has been a trial/failure on one preferred product.	Sancuso® will be approved if the patient is currently undergoing cancer chemotherapy and one of the following is true: o The provider wishes to use this product to avoid the need for IV anti-emetics; OR o There has been a trial/failure on one preferred product.

Description of Recommendation	Final Decision (s)
Oral Antiemetics: NK-1 Antagonists 1. DMS to select preferred agent (s) based on economic evaluation; however at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Oral Anti-Emetics: NK_1 antagonist, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Emend® **Non Preferred** Agent (s) N/A
Oral Antiemetics: Δ-9-THC Derivatives 1. DMS to select preferred agent (s) based on economic evaluation; however at least one unique chemical entity should be preferred. 2. All agents in this category should require Prior Authorization to prevent miss-use. 3. For any new chemical entity in the Oral Anti-Emetics: Δ-9-THC Derivatives require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) dronabinol **Non Preferred** Agent (s) Cesamet® Marinol®
Oral Antiemetics: Δ-9-THC Clinical Criteria Cannabinoids will be approved if one of the following is true: 1. Nausea and vomiting associated with cancer chemotherapy AFTER failure to respond adequately to at least ONE other anti-emetic therapy; OR 2. Anorexia associated with weight loss in patients with AIDS or cancer (dronabinol ONLY).	Cannabinoids will be approved if one of the following is true: 1. Nausea and vomiting associated with cancer chemotherapy AFTER failure to respond adequately to at least ONE other anti-emetic therapy; OR 2. Anorexia associated with weight loss in patients with AIDS or cancer (dronabinol ONLY).
H_2 Receptor Antagonists 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 will require Prior Authorization. 3. For any new chemical entity in the H_2 Receptor Antagonists class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) cimetidine famotidine ranitidine **Non Preferred** Agent (s) Axid® Pepcid® Nizatidine Zantac®

Description of Recommendation	Final Decision (s)
Anti-Ulcer Protectants 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Anti-Ulcer Protectants class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) misoprostol sucralfate **Non Preferred** Agent (s) Carafate® Cytotec®
Combination Products for H. pylori 1. DMS to select preferred agent (s) based on economic evaluation; however, at least Prevpac® should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Agents in this class should have quantity limits based on the FDA-approved maximum dose. 4. For any new chemical entity in the Combination Products for H. pylori class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Helidac® Prevpac® **Non Preferred** Agent (s) Pylera®

Description of Recommendation	Final Decision (s)
Antispasmodics / Anticholinergics 1. DMS to select preferred agent (s) based on economic evaluation. However, at least one formulation of atropine, dicyclomine, glycopyrrolate, hyoscyamine, methscopolamine, and scopolamine should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Antispasmodics / Anticholinergics class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) atropine sulfate dicyclomine hyoscyamine glycopyrrolate methscopolamine propantheline Transderm-Scop® **Non Preferred** Agent (s) Anaspaz® Bentyl® Cantil® chlordiazepoxide/clidinium Cuvposa® Librax® Pamine® Pamine Forte® PB-Hyos® Quadrapax® Robinul® Robinul Forte® Sal-Tropine® Scopace®
Antidiarrheals 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 will require Prior Authorization. 3. For any new chemical entity in the Antidiarrheals class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) diphenoxylate with atropine loperamide **Non Preferred** Agent (s) Lomotil® Motofen® paregoric

Description of Recommendation	Final Decision (s)
Laxatives and Cathartics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities should be preferred. The preferred products should include lactulose, polyethylene glycol, and one agent used for bowel evacuation or colon cleansing. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Laxatives and Cathartics class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Amitiza® lactulose Moviprep® Osmoprep® PEG 3350/Electrolyte PEG 3350/Na Sulf, Bicarb. Cl/KCl polyethylene glycol Sod Chloride /NAHCO3/KCl/PEGS Visicol® **Non Preferred** Agent (s) Colyte® with flavoring Gavilyte-C® Gavilyte-G® Gavilyte-N® Glycolax® Golytely® Halflytely-Bisacodyl Bowel Kit® Kristalose® Miralax® Nulytely® with Flavor Packs OCL® Relistor® Suprep® Trilyte® with Flavor Packets
Amitiza® Clinical Criteria Amitiza® should be approved for the following diagnoses: • Irritable Bowel Syndrome with constipation; OR • Chronic Idiopathic Constipation after failure of one laxative.	Amitiza® will be approved for the following diagnoses: • Irritable Bowel Syndrome with constipation; OR • Chronic Idiopathic Constipation after failure of one laxative.

Description of Recommendation	Final Decision (s)
Relistor® Clinical Criteria Relistor® should be approved if all of the following criteria are met: • Diagnosis of opioid-induced constipation; AND • Patient has advanced illness, which is defined as a terminal disease (incurable cancer or other end-stage disease); AND • Trial and failure (unless contraindicated or intolerant to) of an agent in each of the following drug classes: o Stool softening agent; AND o Peristalsis-inducing agent.	Relistor® will be approved if all of the following criteria are met: • Diagnosis of opioid-induced constipation; AND • Patient has advanced illness, which is defined as a terminal disease (incurable cancer or other end-stage disease); AND • Trial and failure (unless contraindicated or intolerant to) of an agent in each of the following drug classes: o Stool softening agent; AND o Peristalsis-inducing agent.