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 March 15, 2012 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
New Products to Market: Zelboraf™ Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Zelboraf™ after confirmation that the serine-threonine protein kinase BRAF **(**BRAF) V600E mutation has been detected by an FDA-approved test.	Zelboraf™ will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Zelboraf™ will only be approved after confirmation that the serine-threonine protein kinase BRAF **(**BRAF) V600E mutation has been detected by an FDA-approved test.
New Products to Market: Xalkori® Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Xalkori® after confirmation of non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.	Xalkori® will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Xalkori® will only be approved after confirmation of non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
New Products to Market: Jakafi™ Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Jakafi™ should only be approved for a diagnosis of intermediate or high risk myelofibrosis (MF).	Jakafi™ will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Jakafi™ will only be approved for a diagnosis of intermediate or high risk myelofibrosis (MF).
New Products to Market: Xarelto® Place this product preferred in the PDL class titled Anticoagulants.	Xarelto® will be placed preferred in the PDL class titled Anticoagulants.
New Products to Market: Juvisync™ Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.	Juvisync™ will be placed preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Dificid™ Place this product non preferred in the PDL class titled Macrolides; however, approve Dificid™ after trial and failure of oral vancomycin or metronidazole.	Dificid™ will be placed non preferred in the PDL class titled Macrolides; however, Dificid™ will only be approved after trial and failure of oral vancomycin or metronidazole.
New Products to Market: Arcapta™ Place this product non preferred with appropriate quantity limits in the PDL class titled Beta Agonist, Long-Acting**.**	Arcapta™ will be placed non preferred with appropriate quantity limits in the PDL class titled Beta Agonist, Long-Acting**.**
New Products to Market: Brilinta™ Place this product preferred in the PDL class titled Platelet Inhibitors; however, only approve Brilinta™ for a diagnosis of acute coronary syndrome (ACS).	Brilinta™ will be placed preferred in the PDL class titled Platelet Inhibitors; however, Brilinta™ will only be approved for a diagnosis of acute coronary syndrome (ACS).

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New Products to Market: Duexis® Place this product non preferred in the PDL class titled Non-Steroidal Anti-Inflammatory Drugs; however, only approve Duexis® for patients who cannot take ibuprofen and famotidine as individual components.	Duexis® will be placed non preferred in the PDL class titled Non-Steroidal Anti-Inflammatory Drugs; however, Duexis® will only be approved for patients who cannot take ibuprofen and famotidine as individual components.
New Products to Market: Onfi™ Place this product non preferred in the PDL class titled Anticonvulsants: First Generation.	Onfi™ will be placed non preferred in the PDL class titled Anticonvulsants: First Generation.
New Products to Market: Edarbyclor™ Place this product non preferred in the PDL class titled: Angiotensin Receptor Blockers + Diuretic.	Edarbyclor™ will be placed non preferred in the PDL class titled: Angiotensin Receptor Blockers + Diuretic.
New Products to Market: Dutoprol™ Place this product non preferred in the PDL class titled: Beta Blockers + Diuretics.	Dutoprol™ will be placed non preferred in the PDL class titled: Beta Blockers + Diuretics.
Hepatitis C: Oral Protease Inhibitors 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. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class to ensure appropriate utilization. 5. Continue quantity and duration limitations based on approved maximum dose and duration. 6. For any new chemical entity in the Hepatitis C: Oral Protease Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Incivek™ Victrelis™ **Non Preferred Agent (s)** N/A
Hepatitis C: Incivek™ Clinical Criteria 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™ will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon.
Hepatitis C: Victrelis™ Clinical Criteria 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 the patient is receiving concurrent therapy with ribavirin and peginterferon.	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.

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Hepatitis C: Interferons 1. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa-2a and peginterferon alfa-2b should be preferred. 2. Agents not selected as preferred will be considered non preferred. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class to ensure appropriate utilization. 5. Continue current quantity limits based on maximum approved dose. 6. For any new chemical entity in the Hepatitis C: Interferons class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** PEGASYS® PEGASYS® ProClick PEGIntron™ PEGIntron™ Redipen® **Non Preferred Agent (s)** Infergen®
Hepatitis C: Interferons Clinical Criteria After the initial 18 weeks of therapy, interferons should be approved if there is at least a 2 logarithmic unit decrease in HCV RNA levels at treatment week 12. ***LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT*** 1. Interferon alfacon-1 a. IFN naïve – 24 weeks total therapy b. INF relapse – 48 weeks total therapy 2. Peginterferon alfa-2a OR 2b a. Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy b. Genotype 2, 3 – 24 weeks total therapy	**Hepatitis C: Interferons Clinical Criteria** After the initial 18 weeks of therapy, interferons will be approved if there is at least a 2 logarithmic unit decrease in HCV RNA levels at treatment week 12. ***LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT*** 1. Interferon alfacon-1 a. IFN naïve – 24 weeks total therapy b. INF relapse – 48 weeks total therapy 2. Peginterferon alfa-2a OR 2b a. Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy b. Genotype 2, 3 – 24 weeks total therapy
Hepatitis C: Ribavirins 1. DMS to select preferred agent (s) based on economic evaluation; however, at least ribavirin should be preferred. 2. Agents not selected as preferred will be considered non preferred. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class of ribavirins to ensure appropriate utilization. 5. For any new chemical entity in the Hepatitis C: Ribavirins class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Ribasphere™ 400 mg ribavirin tablets **Non Preferred Agent (s)** Copegus® Rebetol® Ribasphere™ 600 mg Ribapack™ ribavirin capsules

Description of Recommendation	Final Decision (s)
Hepatitis C: Ribavirins Clinical Criteria Ribavirins should pay at point-of-sale if there is concurrent interferon therapy in history.	Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.
Topical Retinoids 1. DMS to select preferred agent (s) based on economic evaluation; however, at least tretinoin 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 Topical Retinoid class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** adapalene Retin-A Micro® tretinoin **Non Preferred Agent (s)** Atralin™ Avita® Differin® Epiduo™ Retin-A® Retin-A Micro® Pump Tazorac® Veltin™ Ziana™
Beta Agonists, Short-Acting 1. DMS to select preferred agent (s) based on economic evaluation; however, at least a nebulized and metered dose inhaler formulation of albuterol must be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on inhaled versions of Short-Acting $Beta_2$ Adrenergic Agents. 4. For any new chemical entity in the Short-Acting $Beta_2$ Adrenergic Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** albuterol inhalation solution albuterol low-dose inhalation solution albuterol oral syrup, tablets Proventil HFA® ProAir HFA® terbutaline tablets **Non Preferred Agent (s)** levalbuterol inhalation solution Maxair® Autohaler metaproterenol inhalation solution metaproterenol oral tablets Ventolin HFA® Xopenex® Xopenex® HFA

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Beta Agonists, Long-Acting 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. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Long-Acting $Beta_2$ Adrenergic Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Foradil® Aerolizer® Serevent® Diskus **Non Preferred Agent (s)** Arcapta™ Brovana® Perforomist®
Corticosteroids, Inhaled 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. Continue to allow budesonide respules without PA for patients less than 8 years of age. 5. For any new chemical entity in the Inhaled Corticosteroid class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Asmanex® Twisthaler budesonide respules Flovent Diskus® Flovent HFA® QVAR™ **Non Preferred Agent (s)** Alvesco® Pulmicort Flexhaler® Pulmicort Respules®
Beta Agonists: Combination Products 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity FDA-approved for COPD should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Beta Agonist: Combination class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Advair® Diskus Advair® HFA Dulera® Symbicort® **Non Preferred Agent (s)** N/A

Description of Recommendation	Final Decision (s)
Leukotriene Modifiers 1. DMS to select preferred agent (s) based on economic evaluation; however, at least montelukast should be preferred. 2. Continue to require Prior Authorization for all agents in this class. 3. Continue quantity limits on agents in this class based on maximum approved dose. 4. For any new chemical entity in the Leukotriene Modifiers class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Singulair® zafirlukast **Non Preferred Agent (s)** Accolate® Zyflo CR®
COPD Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. At least one combination product and tiotropium should be among the preferred products. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the COPD Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** albuterol/ipratropium inhalation solution Atrovent® HFA Combivent® ipratropium inhalation solution Spiriva Handihaler® **Non Preferred Agent (s)** Daliresp™ Duoneb®
Corticosteroids, Intranasal 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 to maintain quantity limits based on maximum daily dose. 4. For any new chemical entity in the Corticosteroids, Intranasal class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** fluticasone propionate Nasonex® **Non Preferred Agent (s)** Beconase AQ® Flonase® flunisolide Nasacort AQ® Omnaris™ Rhinocort Aqua® triamcinolone Veramyst®

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Antihistamines, Intranasal 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 require PA. 3. For any new chemical entity in the Intranasal Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Astepro® azelastine **Non Preferred Agent (s)** Astelin® Patanase™
Anticholinergics, Intranasal 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 require PA. 3. For any new chemical entity in the Intranasal Anticholinergics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** ipratropium nasal spray **Non Preferred Agent (s)** Atrovent®
Antihistamines, Non-Sedating 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Non-Sedating Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** cetirizine OTC loratadine OTC loratadine/pseudoephedrine OTC **Non Preferred Agent (s)** Allegra® Allegra-D® 12-Hour Allegra-D® 24-Hour cetirizine syrup Clarinex® Clarinex-D® 12-Hour Clarinex-D® 24-Hour fexofenadine fexofenadine/pseudoephedrine 12-Hour fexofenadine/pseudoephedrine 24-Hour levocetirizine Semprex D® Xyzal®

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Antibiotics, Inhaled 1. DMS to select preferred agent (s) based on economic evaluation; however, at least tobramycin 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 Inhaled Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** TOBI® **Non Preferred Agent (s)** Cayston®
Self Injectable Epinephrine 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one product available in an adult and pediatric dose 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 Self-Injectable Epinephrine Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Epi Pen® Epi Pen® Jr. Twinject® Twinject® Jr. **Non Preferred Agent (s)** N/A
Cialis® Clinical Criteria Cialis® will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both: • An alpha blocker for one month; AND • A 5-Alpha Reductase Inhibitor for four months. Cialis® should not be used in combination with an alpha blocker.	Cialis® will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both: • An alpha blocker for one month; AND • A 5-Alpha Reductase Inhibitor for four months. Cialis® should not be used in combination with an alpha blocker.

Description of Recommendation	Final Decision (s)
BOTOX™ Clinical Criteria Diagnosis to approve: • Blepharospasm • Cervical dystonia • Severe primary axillary hyperhidrosis • Strabismus • Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: o Muscle relaxants o Bracing o Splinting o Occupational Therapy o Physical Therapy • Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): o Prophylactic therapy with at least two (2) of the following: ▪ Beta-blocker ▪ Amitriptyline ▪ Valproate ▪ Topiramate o Tried and failed abortive therapy with two triptans. • Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication.	BOTOX™ will be approved for the following diagnoses: • Blepharospasm • Cervical dystonia • Severe primary axillary hyperhidrosis • Strabismus • Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: o Muscle relaxants o Bracing o Splinting o Occupational Therapy o Physical Therapy • Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): o Prophylactic therapy with at least two (2) of the following: ▪ Beta-blocker ▪ Amitriptyline ▪ Valproate ▪ Topiramate o Tried and failed abortive therapy with two triptans. • Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication.

Description of Recommendation	Final Decision (s)
Synagis® Clinical Criteria Approval should be granted if the recipient has at least **one** of the following indications: 1. Recipient is less than 24 months of age at the start of RSV season (i.e., November 1st) and has chronic lung disease that has required medical treatment (supplemental oxygen, bronchodilators, diuretics or chronic corticosteroids) in the preceding 6 months. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 2. Recipient is less than 24 months of age at the start of RSV season and has one of the following: a. Hemodynamically significant cyanotic or acyanotic congenital heart disease. b. Receives medications to control CHF or cardiomyopathy. c. Has moderate to severe pulmonary hypertension. d. Has undergone cardio-pulmonary bypass surgery. For this patient population, the dose should be given as soon as the patient is medically stable, even if sooner than a month from the previous dose] If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 3. Recipient is less than or equal to 12 months of age at the start of the RSV season **and** was born at less than or equal to 28 weeks' gestation. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 4. Recipient is less than or equal to 6 months of age at the start of the RSV season **and** was born at 29 to 32 (31 weeks, 6 days or less) weeks' gestation. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 5. Recipient is less than or equal to 3 months of age at the start of the RSV season **and** was born between 32 and <35 (32 weeks, 0 days to 34 weeks, 6 days) weeks' gestation **and** has one of the following other risk factors: a. Attends child care, defined as a home or facility where care is provided for any number of infants or young toddlers.	Synagis® will be approved if the recipient has at least **one** of the following indications: 1. Recipient is less than 24 months of age at the start of RSV season (i.e., November 1st) and has chronic lung disease that has required medical treatment (supplemental oxygen, bronchodilators, diuretics or chronic corticosteroids) in the preceding 6 months. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 2. Recipient is less than 24 months of age at the start of RSV season and has one of the following: a. Hemodynamically significant cyanotic or acyanotic congenital heart disease. b. Receives medications to control CHF or cardiomyopathy. c. Has moderate to severe pulmonary hypertension. d. Has undergone cardio-pulmonary bypass surgery. For this patient population, the dose should be given as soon as the patient is medically stable, even if sooner than a month from the previous dose] If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 3. Recipient is less than or equal to 12 months of age at the start of the RSV season **and** was born at less than or equal to 28 weeks' gestation. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 4. Recipient is less than or equal to 6 months of age at the start of the RSV season **and** was born at 29 to 32 (31 weeks, 6 days or less) weeks' gestation. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 5. Recipient is less than or equal to 3 months of age at the start of the RSV season **and** was born between 32 and <35 (32 weeks, 0 days to 34 weeks, 6 days) weeks' gestation **and** has one of the following other risk factors:

b. Has a sibling less than 5 years of age. If yes, approve for a maximum of 3 doses to be given between November 1 and March 31. Drug should be discontinued at 3 months of age regardless of number of doses given. 6. Recipient is less than or equal to 12 months of age at onset of RSV season and was born before 35 weeks' (34 weeks, 6 days) gestation who have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31.	a. Attends child care, defined as a home or facility where care is provided for any number of infants or young toddlers. b. Has a sibling less than 5 years of age. If yes, approve for a maximum of 3 doses to be given between November 1 and March 31. Drug should be discontinued at 3 months of age regardless of number of doses given. 6. Recipient is less than or equal to 12 months of age at onset of RSV season and was born before 35 weeks' (34 weeks, 6 days) gestation who have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31.