

# Kentucky Department for Medicaid Services

## Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the September 17, 2009, meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration												
<b><u>Branded Products with Generic components</u></b>	Require prior authorization for the following products: <ul style="list-style-type: none"> <li>• IC400<sup>®</sup></li> <li>• IC800<sup>®</sup></li> <li>• Benziq<sup>®</sup></li> </ul>												
<b><u>New Drugs to Market: Lamictal XR™</u></b>	Based on the Committee's recommendation when this class was reviewed, place this product preferred in the PDL category titled: Anticonvulsants: Second Generation.												
<b><u>New Drugs to Market: Multaq<sup>®</sup></u></b>	Allow this product to pay once the following clinical criteria are met: <p>Multaq<sup>®</sup> will be approved if any <b>one</b> the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Trial and failure of amiodarone via a 90 day electronic look back; OR</li> <li>• Contraindication to amiodarone.</li> </ul>												
<b><u>New Drugs to Market: Cetraxal™</u></b>	Place this product non preferred in the PDL category titled: Otic: Quinolone Antibiotics.												
<b><u>New Drugs to Market: BenzaClin CareKit<sup>®</sup></u></b>	Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne.												
<b><u>New Drugs to Market: Nucynta™</u></b>	Place this product non preferred in the PDL category titled: Narcotics: Short-Acting.												
<b><u>New Drugs to Market: Edluar<sup>®</sup></u></b>	Place this product non preferred in the PDL category titled: Sedative Hypnotic Agents with the following clinical criteria: <p>Edluar<sup>®</sup> will be approved if one of the following criteria is met:</p> <ul style="list-style-type: none"> <li>• Diagnosis of dysphagia via an ICD-9 Override, OR</li> </ul> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Diagnosis</th> <th style="text-align: center;">ICD-9 Code</th> </tr> </thead> <tbody> <tr> <td>dysphagia</td> <td style="text-align: center;">787.2</td> </tr> <tr> <td>dysphagia - functional, hysterical, or nervous</td> <td style="text-align: center;">300.11</td> </tr> <tr> <td>dysphagia - psychogenic</td> <td style="text-align: center;">306.4</td> </tr> <tr> <td>dysphagia - sideropenic</td> <td style="text-align: center;">280.8</td> </tr> <tr> <td>dysphagia - spastica</td> <td style="text-align: center;">530.5</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>• Trial and failure of 2 preferred sedative hypnotics, one of which must be zolpidem.</li> </ul>	Diagnosis	ICD-9 Code	dysphagia	787.2	dysphagia - functional, hysterical, or nervous	300.11	dysphagia - psychogenic	306.4	dysphagia - sideropenic	280.8	dysphagia - spastica	530.5
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<b><u>New Drugs to Market: Adcirca™</u></b>	Place this product non preferred in the PDL category titled: Agents for Pulmonary Hypertension with the following clinical criteria: <p>Adcirca™ will be approved if both of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Diagnosis of pulmonary hypertension via an ICD-9 Override (416.0, 416.8), AND</li> <li>• Trial and failure of sildenafil via a 90 day electronic look back.</li> </ul>												

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<b><u>New Drugs to Market: Acuvail™</u></b>	Place this product non preferred in the PDL category titled: Ophthalmic NSAIDs.
<b><u>New Drugs to Market: Effient™</u></b>	Place this product non preferred in the PDL category titled: Platelet Inhibitors; however, allow for its use after trial and failure of or contraindication to clopidogrel.
<b><u>Protein Tyrosine Kinase Inhibitors</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least imatinib should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. DMS to allow continuation of therapy for existing users of non preferred products via a 90 day look back.</li> <li>4. For any new chemical entity in the Protein Tyrosine Kinase Inhibitor class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Ranexa® Clinical Criteria</u></b>	<p>Ranexa® (ranolazine) will be approved if the patient has a history of one agent in any of the following drug classes within the past 90 days (unless ALL are contraindicated).</p> <ul style="list-style-type: none"> <li>• Beta Blocker</li> <li>• Nitrate</li> <li>• Calcium Channel Blocker</li> </ul>
<b><u>Lidoderm® Clinical Criteria</u></b>	<p>Lidoderm® will be approved if any one of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR</li> <li>• History of one agent in any of the following medication classes in the past 90 days: <ul style="list-style-type: none"> <li>○ Tricyclic antidepressant</li> <li>○ Anticonvulsant</li> <li>○ SNRI</li> </ul> </li> </ul>
<b><u>Hepatitis C: Pegylated Interferons</u></b>	<ol style="list-style-type: none"> <li>1. Rename the category Hepatitis C: Interferons.</li> <li>2. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa-2a and peginterferon alfa-2b should be preferred.</li> <li>3. Agents not selected as preferred will be considered non preferred.</li> <li>4. PDL selected agents will apply for any new courses of therapy only.</li> <li>5. Place clinical prior authorization around the entire class to ensure appropriate utilization.</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>

Item	Options for Consideration
<p align="center"><b><u>Hepatitis C: Pegylated Interferons Clinical Criteria</u></b></p>	<p>All preferred and non-preferred pegylated interferons will require a prior authorization after the initial 16 weeks of therapy.</p> <p><b><u>After the initial 16 weeks of therapy pegylated interferons will be approved if:</u></b></p> <ol style="list-style-type: none"> <li>1. HCV RNA Assay results obtained prior to initiation of therapy <b>AND</b> 12 weeks after initiation of therapy must be provided. If the difference between the two assays is at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), <b>THEN</b> approve for duration of therapy as defined below.</li> <li>2. If the assays were done <b>BUT</b> the difference between the two assays <b>WAS NOT</b> at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), <b>THEN</b> refer the request to a clinical pharmacist who will deny the request.</li> <li>3. If there is any other valid medical reason why the patient should require this therapy, a clinical pharmacist may approve the request for the total length of therapy as listed below.</li> </ol> <p><b><i>LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT</i></b></p> <ol style="list-style-type: none"> <li>1. Interferon alfacon-1 <ol style="list-style-type: none"> <li>a. IFN naïve – 24 weeks total therapy</li> <li>b. INF relapse – 48 weeks total therapy</li> </ol> </li> <li>2. Peginterferon alfa-2a OR 2b <ol style="list-style-type: none"> <li>a. Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy</li> <li>b. Genotype 2, 3 – 24 weeks total therapy</li> </ol> </li> </ol>
<p align="center"><b><u>Hepatitis C: Ribavirins</u></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. PDL selected agents will apply for any new courses of therapy only.</li> <li>4. Place clinical prior authorization around the entire class of ribavirins to ensure appropriate utilization.</li> <li>5. 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 align="center"><b><u>Hepatitis C: Ribavirins Clinical Criteria</u></b></p>	<p>Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.</p>

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<p align="center"><b><u>Antihyperkinesia 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 short-acting, one intermediate-acting and one long-acting formulation of methylphenidate and dextroamphetamine should be preferred.</li> <li>2. Require appropriate ICD-9 on all prescriptions for agents within this class.</li> <li>3. If atomoxetine is non preferred, allow for its use in patients with ADHD/ADD and a history of substance abuse or diversion on the part of the patient or the caregiver, mood disorder or tic disorder.</li> <li>4. Continue to require prior authorization for modafinil and armodafinil to ensure utilization in FDA-approved indications only.</li> <li>5. Place quantity limits on all agents based on the American Academy of Child and Adolescent Psychiatry and FDA-approved maximum recommended dose.</li> <li>6. Allow only one agent at a time for an extended release product and one agent at a time for an immediate release product unless switching agents due to therapeutic failure.</li> <li>7. Allow continuation of therapy for non preferred products via a 90 day look back.</li> <li>8. For any new chemical entity in the Antihyperkinesia class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>																				
<p align="center"><b><u>Antihyperkinesia Agents Clinical Criteria</u></b></p>	<p>Diagnosis to Approve via an ICD-9 Override:</p> <table border="1" data-bbox="456 898 1552 1383"> <thead> <tr> <th data-bbox="456 898 1013 932"><b><u>Diagnosis</u></b></th> <th data-bbox="1013 898 1552 932"><b><u>ICD-9</u></b></th> </tr> </thead> <tbody> <tr> <td data-bbox="456 932 1013 1003" rowspan="5">Attention Deficit/Hyperactivity Disorder (ADHD)</td> <td data-bbox="1013 932 1552 961">314.1</td> </tr> <tr> <td data-bbox="1013 961 1552 991">314.01</td> </tr> <tr> <td data-bbox="1013 991 1552 1020">314.2</td> </tr> <tr> <td data-bbox="1013 1020 1552 1050">314.8</td> </tr> <tr> <td data-bbox="1013 1050 1552 1079">314.9</td> </tr> <tr> <td data-bbox="456 1079 1013 1108">Attention Deficit Disorder (ADD)</td> <td data-bbox="1013 1079 1552 1108">314.00</td> </tr> <tr> <td data-bbox="456 1108 1013 1180" rowspan="3">Narcolepsy</td> <td data-bbox="1013 1108 1552 1138">347.00</td> </tr> <tr> <td data-bbox="1013 1138 1552 1167">347.01</td> </tr> <tr> <td data-bbox="1013 1167 1552 1197">347.11</td> </tr> <tr> <td data-bbox="456 1197 1013 1268" rowspan="3">Sleep apnea/hypoapnea syndrome</td> <td data-bbox="1013 1197 1552 1226">780.57</td> </tr> <tr> <td data-bbox="1013 1226 1552 1255">780.51</td> </tr> <tr> <td data-bbox="1013 1255 1552 1285">780.53</td> </tr> <tr> <td data-bbox="456 1285 1013 1314">Shift work sleep disorder</td> <td data-bbox="1013 1285 1552 1314">307.45</td> </tr> </tbody> </table> <p data-bbox="456 1423 1552 1484">**Agents may be approved for other diagnosis via the prior authorization process based on a review of the current literature by a clinical pharmacist.</p>	<b><u>Diagnosis</u></b>	<b><u>ICD-9</u></b>	Attention Deficit/Hyperactivity Disorder (ADHD)	314.1	314.01	314.2	314.8	314.9	Attention Deficit Disorder (ADD)	314.00	Narcolepsy	347.00	347.01	347.11	Sleep apnea/hypoapnea syndrome	780.57	780.51	780.53	Shift work sleep disorder	307.45
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<p><b><u>Antihyperkinesia</u></b>  <b><u>Agents Clinical Criteria</u></b>  <b><u>Continued</u></b></p>	<p>Quantity Limits/Maximum Daily Dose</p> <ul style="list-style-type: none"> <li>• Adderall® 60 mg per day</li> <li>• Adderall® XR 60 mg per day</li> <li>• Concerta® 108 mg per day</li> <li>• Daytrana™ 30 mg per day</li> <li>• Desoxyn® 25 mg per day</li> <li>• Dexedrine® IR 60 mg per day</li> <li>• Dexedrine® ER 60 mg per day</li> <li>• dexamethylphenidate 50 mg per day</li> <li>• dextroamphetamine IR 60 mg per day</li> <li>• dextroamphetamine ER 60 mg per day</li> <li>• DextroStat® 60 mg per day</li> <li>• Focalin™ 50 mg per day</li> <li>• Focalin™ XR 50 mg per day</li> <li>• Metadate® CD 100 mg per day</li> <li>• Metadate® ER 100 mg per day</li> <li>• methamphetamine 25 mg per day</li> <li>• Methylin® 100 mg per day</li> <li>• Methylin® ER 100 mg per day</li> <li>• methylphenidate IR 100 mg per day</li> <li>• methylphenidate SR 100 mg per day</li> <li>• mixed amphetamine salt IR 60 mg per day</li> <li>• mixed Amphetamine salt ER 60 mg per day</li> <li>• Nuvigil® 150 mg per day</li> <li>• Procentra™ 60 mg per day</li> <li>• Provigil® 400 mg per day</li> <li>• Ritalin® 100 mg per day</li> <li>• Ritalin® LA 100 mg per day</li> <li>• Ritalin® SR 100 mg per day</li> <li>• Strattera® 100 mg per day</li> <li>• Vyvanse™ 70 mg per day</li> </ul> <p>Therapeutic Duplication  Prior authorization will be required for more than one long-acting (Adderall® XR, Concerta®, Daytrana™, Desoxyn®, Dexedrine® ER, dextroamphetamine ER, Metadate® CD, Metadate® ER, methamphetamine, Focalin™ XR, Methylin® ER, methylphenidate SR, mixed amphetamine salt ER, Procentra™, Ritalin® LA, Ritalin® SR, Strattera®, Vyvanse™), or more than one short-acting (Adderall®, amphetamine salt combo, Dexedrine® IR, dexamethylphenidate, dextroamphetamine IR, DextroStat®, Focalin™, Methylin®, methylphenidate, mixed amphetamine salt IR, Ritalin®) stimulant at a time.</p>

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<p align="center"><b><u>Antihyperkinesia Agents, Special Formulations Clinical Criteria</u></b></p>	<p>Daytrana™, Methylin® Solution, Methylin® Chewable Tabs, or Procentra™ will be approved if either of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Trial and failure of two preferred products, one of which must be the same chemical as the requested medication; OR</li> <li>• Inability to swallow/tolerate PO/whole tablets/capsules <ul style="list-style-type: none"> <li>○ For Daytrana™, inability to swallow/tolerate PO medications; OR</li> <li>○ For Methylin® Solution, Methylin® Chewable Tabs, or Procentra™, inability to swallow tablets or capsules whole.</li> </ul> </li> </ul>														
<p align="center"><b><u>Strattera® Clinical Criteria</u></b></p>	<p>Strattera® (atomoxetine) will be approved if both of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Diagnosis of:</li> </ul> <table border="1" data-bbox="565 667 1550 913"> <thead> <tr> <th data-bbox="565 667 1079 701"><b><u>Diagnosis</u></b></th> <th data-bbox="1079 667 1550 701"><b><u>ICD-9</u></b></th> </tr> </thead> <tbody> <tr> <td data-bbox="565 701 1079 735">Attention Deficit/Hyperactivity Disorder (ADHD)</td> <td data-bbox="1079 701 1550 735">314.1</td> </tr> <tr> <td data-bbox="565 735 1079 768"></td> <td data-bbox="1079 735 1550 768">314.01</td> </tr> <tr> <td data-bbox="565 768 1079 802"></td> <td data-bbox="1079 768 1550 802">314.2</td> </tr> <tr> <td data-bbox="565 802 1079 835"></td> <td data-bbox="1079 802 1550 835">314.8</td> </tr> <tr> <td data-bbox="565 835 1079 869"></td> <td data-bbox="1079 835 1550 869">314.9</td> </tr> <tr> <td data-bbox="565 869 1079 903">Attention Deficit Disorder (ADD)</td> <td data-bbox="1079 869 1550 903">314.00</td> </tr> </tbody> </table> <p>AND;</p> <ul style="list-style-type: none"> <li>• Any one of the following criteria: <ul style="list-style-type: none"> <li>○ Trial and failure of one preferred antihyperkinesia agents in the past 365 days OR</li> <li>○ History of substance abuse or diversion on the part of the patient or caregiver; OR</li> <li>○ History of tic disorder, including Tourette's; OR</li> <li>○ Co-morbid mood disorder.</li> </ul> </li> </ul>	<b><u>Diagnosis</u></b>	<b><u>ICD-9</u></b>	Attention Deficit/Hyperactivity Disorder (ADHD)	314.1		314.01		314.2		314.8		314.9	Attention Deficit Disorder (ADD)	314.00
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<p align="center"><b><u>Provigil® / Nuvigil® Clinical Criteria</u></b></p>	<p>Provigil® (modafinil) / Nuvigil® (armodafinil) will be approved if both of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• One of the following approvable diagnosis (via ICD-9 override):</li> </ul> <table border="1" data-bbox="565 1318 1550 1564"> <tbody> <tr> <td data-bbox="565 1318 1079 1352">Narcolepsy</td> <td data-bbox="1079 1318 1550 1352">347.00</td> </tr> <tr> <td data-bbox="565 1352 1079 1386"></td> <td data-bbox="1079 1352 1550 1386">347.01</td> </tr> <tr> <td data-bbox="565 1386 1079 1419"></td> <td data-bbox="1079 1386 1550 1419">347.11</td> </tr> <tr> <td data-bbox="565 1419 1079 1453">Sleep apnea/hypoapnea syndrome</td> <td data-bbox="1079 1419 1550 1453">780.57</td> </tr> <tr> <td data-bbox="565 1453 1079 1486"></td> <td data-bbox="1079 1453 1550 1486">780.51</td> </tr> <tr> <td data-bbox="565 1486 1079 1520"></td> <td data-bbox="1079 1486 1550 1520">780.53</td> </tr> <tr> <td data-bbox="565 1520 1079 1554">Shift work sleep disorder</td> <td data-bbox="1079 1520 1550 1554">307.45</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>• For Nuvigil® (armodafinil) ONLY, trial and failure of Provigil® (modafinil) via a 90 day look back</li> </ul>	Narcolepsy	347.00		347.01		347.11	Sleep apnea/hypoapnea syndrome	780.57		780.51		780.53	Shift work sleep disorder	307.45
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<p align="center"><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>														

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<b><u>ACE Inhibitors</u></b>	<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 lisinopril, 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 ACE Inhibitor class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>ACE Inhibitor + Diuretic Combinations</u></b>	<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 lisinopril/HCTZ, 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 ACEI + Diuretic Combination class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Antibiotic Agents for Acne</u></b>	<ol style="list-style-type: none"> <li>1. Rename this category Miscellaneous Topical Treatments for Acne.</li> <li>2. DMS to select preferred agent (s) based on economic evaluation; however, at least generic formulations of benzoyl peroxide and one topical antibiotic agent for acne should be preferred.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Miscellaneous Topical Treatments for Acne class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Oral Retinoids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least acitretin and isotretinoin 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 Retinoid class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Isotretinoin Clinical Criteria</u></b>	<p>Since the iPLEDGE system already restricts the use of these products, allow them to be subject to the general PDL criteria if one is chosen to be preferred over another.</p>
<b><u>Topical Retinoids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least tretinoin 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 Retinoid class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Corticosteroids, Intranasal</u></b>	<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. Continue to maintain quantity limits based on maximum daily dose.</li> <li>4. For any new chemical entity in the Corticosteroids, Intranasal class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

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<b><u>Amylin Analog</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation.</li> <li>2. Allow for use of pramlintide with active insulin therapy only.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Amylin Analog class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Symlin® clinical Criteria</u></b>	Symlin® will be approved if insulin is seen in history within the past 90 days.
<b><u>Incretin Mimetic</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. Continue current step therapy for exenatide.</li> <li>4. For any new chemical entity in the Incretin Mimetics class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Byetta™ Clinical Criteria</u></b>	Byetta™ will be approved if metformin or a sulfonylurea is seen in history within the past 90 days.
<b><u>Alpha Glucosidase Inhibitors</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent 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 Alpha-Glucosidase Inhibitor class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Biguanides</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least metformin 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 Diabetes: Biguanides class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Meglitinides</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent 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 Meglitinides class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Sulfonylureas and Combinations</u></b>	<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 and one combination 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 Sulfonylureas and Combination class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

Item	Options for Consideration
<b><u>Thiazolidinediones</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least pioglitazone should be preferred.</li> <li>2. Continue quantity limits based on maximum recommended dose.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Thiazolidinedione Combinations</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two combination products containing pioglitazone should be preferred.</li> <li>2. Continue quantity limits based on maximum recommended dose.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Diabetes: Thiazolidinediones Combination class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Bone: Calcitonins</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one 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 Bone: Calcitonins class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Immunomodulators</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two self administrable products, one of which must be etanercept, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require trial and failure of preferred product (s) with a FDA-approved indication for the requested diagnosis.</li> <li>3. All agents in the category should be approved for their FDA-approved indications only.</li> <li>4. Maintain quantity limits on agents within the category according to their maximum recommended dose, taking into consideration any escalating doses needed during initial therapy.</li> <li>5. For any new chemical entity in the Immunomodulator class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

Item	Options for Consideration		
<u><b>Immunomodulator Clinical Criteria</b></u>	Drug	Diagnosis	Prior Therapy
	Orencia® (abatacept)	Rheumatoid arthritis	Trial and failure of 1 DMARD
		Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD
	Humira® (adalimumab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD
		Ankylosing Spondylitis	None
		Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
		Crohn's Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> <li>• 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids – examples: Cortenema, Prednisone</li> <li>• Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li> </ul>
		Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Amevive® (alefacept)	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> </ul>

		<ul style="list-style-type: none"> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>	
	Kineret® (anakinra)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
	Cimzia® (certolizumab pegol)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Crohn's Disease	<p>Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive):</p> <ul style="list-style-type: none"> <li>• 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids – examples: Cortenema, Prednisone</li> <li>• Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li> </ul>
	Enbrel (etanercept)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD
		Ankylosing Spondylitis	None
		Plaque Psoriasis	<p>Trial and failure of two of the following therapies:</p> <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
		Psoriatic Arthritis	<p>Trial and failure of one of the following treatment:</p> <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Simponi™ (golimumab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Ankylosing Spondylitis	None
		Psoriatic Arthritis	<p>Trial and failure of one of the following treatment:</p> <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> </ul>

			<ul style="list-style-type: none"> <li>• Intra-articular corticosteroid</li> </ul>
Remicade® (infliximab)	Rheumatoid Arthritis		Trial and failure of 1 DMARD
	Ankylosing Spondylitis		None
	Plaque Psoriasis		Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
	Crohn's Disease		Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> <li>• 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids – examples: Cortenema, Prednisone</li> <li>• Immunosuppressives – examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li> </ul>
	Ulcerative Colitis		Trial and failure of one of the following treatments: <ul style="list-style-type: none"> <li>• Corticosteroid</li> <li>• Immunosuppressant</li> </ul>
	Fistulizing Crohn's Disease		None
	Psoriatic Arthritis		Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
Non preferred products will require no less than a one month trial and failure of one preferred product which is approved for the same diagnosis.			

Item	Options for Consideration
<p align="center"><b><u>Topical Immunomodulator</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 topical immunomodulator 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 align="center"><b><u>Multiple Sclerosis 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 glatiramer, interferon <math>\beta</math>-1b and one interferon <math>\beta</math>-1a product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. Place quantity limits on these products based on maximum recommended dose.</li> <li>4. For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>