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 November 18, 2010 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
Suboxone® / Subutex® Clinical Criteria Length of Authorization: Initially: 2 months at a 10 days supply per fill (10 days supply with 2 refills for 2 months) After the initial 2 months of therapy: 6 months All of the following must be met: 1. Diagnosis of active opiate dependency or opiate dependency on buprenorphine via an ICD-9 submitted with the claim or seen in medical history. 2. Patient must be 16 years of age or older. 3. The prescriber's UIN number must be written on the PA form. 4. There must be evidence of active substance abuse counseling. 5. After 8 months of therapy, patient shows no evidence of drug dependence on alcohol or illicit drugs. 6. Prescriber must perform monthly KASPER report. 7. Prescriber must perform monthly drug screens and must submit that report with each PA request. 8. Request must come from prescriber. Additionally any claim for Suboxone®/Subutex® will require prior approval if there is a claim for any opioid in the past 30 days of history. Prescribers will be made aware of the narcotic in history and overrides will be granted if: • Prescriber verifies knowledge of patient's relapse, and agrees to increase psychosocial counseling; OR • Narcotic analgesic is being used short-term (30 days or less) for an acute injury leading to acute pain.	**Suboxone® / Subutex® Clinical Criteria** Length of Authorization: Initially: 2 months at a 10 days supply per fill (10 days supply with 2 refills for 2 months) After the initial 2 months of therapy: 6 months All of the following must be met: 1. Diagnosis of active opiate dependency or opiate dependency on buprenorphine via an ICD-9 submitted with the claim or seen in medical history. 2. Patient must be 16 years of age or older. 3. The prescriber's UIN number must be written on the PA form. 4. There must be evidence of active substance abuse counseling. 5. After 8 months of therapy, patient shows no evidence of drug dependence on alcohol or illicit drugs. 6. Prescriber must perform monthly KASPER report. 7. Prescriber must perform monthly drug screens and must submit that report with each PA request. 8. Request must come from prescriber. Additionally any claim for Suboxone®/Subutex® will require prior approval if there is a claim for any opioid in the past 30 days of history. Prescribers will be made aware of the narcotic in history and overrides will be granted if: • Prescriber verifies knowledge of patient's relapse, and agrees to increase psychosocial counseling; OR • Narcotic analgesic is being used short-term (30 days or less) for an acute injury leading to acute pain.

Proposed Quantity Limits: • Subutex® o 2 mg: 3 tablets/day o 8 mg: 3 tablets/day • Suboxone® o 2 mg/0.5 mg: 3 tablets/day o 8 mg/2 mg: 3 tablets/day **Tapering Criteria:** After the initial 8 months of therapy, recipients will be required to taper therapy to a level that holds the patient in treatment and suppresses opioid withdrawal effects.	**Quantity Limits:** a. Subutex® o 2 mg: 3 tablets/day o 8 mg: 3 tablets/day b. Suboxone® o 2 mg/0.5 mg: 3 tablets/day o 8 mg/2 mg: 3 tablets/day **Tapering Criteria:** After the initial 8 months of therapy, recipients will be required to taper therapy to a level that holds the patient in treatment and suppresses opioid withdrawal effects.
Branded Products with Generic Components Require prior authorization for the following products: • Clobeta + Plus® • Ketocon + Plus® • Cocet Plus® • Atuss DS®	The following products will require prior authorization: • Clobeta + Plus® • Ketocon + Plus® • Cocet Plus® • Atuss DS®
New Products to Market: Xeomin® Allow this product to pay if one of the following is true: ▪ Diagnosis of cervical dystonia; OR ▪ Diagnosis of blepharospasm after trial and failure of onabotulinumtoxinA (Botox®).	Xeomin® will be approved if one of the following is true: ▪ Diagnosis of cervical dystonia; OR ▪ Diagnosis of blepharospasm after trial and failure of onabotulinumtoxinA (Botox®).
New Products to Market: Gilenya® Prior to approval of fingolimod, require trial and failure of one of the following: • Interferon beta-1a; OR • Interferon beta-1b; OR • Glatiramer acetate.	Gilenya® will be approved after trial and failure of one of the following: • Interferon beta-1a; OR • Interferon beta-1b; OR • Glatiramer acetate.
New Products to Market: Xerese® Place this product non preferred in the PDL class titled Dermatologics: Anti-virals.	Xerese® will be placed non preferred in the PDL class titled Dermatologics: Anti-virals.
New Products to Market: Tribenzor® Place this product non preferred with similar approval criteria in the PDL class titled Angiotensin Receptor Blockers + CCB (DHP).	Tribenzor® will be placed non preferred with similar approval criteria in the PDL class titled Angiotensin Receptor Blockers + CCB (DHP).
New Products to Market: Tekamlo® Place this product non preferred, unless cost parity to Tekturna®, with similar approval criteria in the PDL class titled Direct Renin Inhibitors.	Tekamlo® will be placed preferred with similar approval criteria in the PDL class titled Direct Renin Inhibitors.

Description of Recommendation	Final Decision (s)
Typical Antipsychotics 1. DMS to select preferred agent(s) based on economic evaluation; however, at least four unique chemical entities, at least one representing an agent from each of the potency groups, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization 3. Allow continuation of therapy for non preferred single source branded products via a 90 day look back. 4. For any new chemical entity in the Antipsychotics: Typical class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) amitriptyline/perphenazine chlorpromazine fluphenazine haloperidol loxapine Moban® Orap® perphenazine thiothixene thioridazine trifluoperazine **Non Preferred** Agent (s) Loxitane® Navane®
Atypical Antipsychotics 1. DMS to select preferred agent(s) based on economic evaluation; however, at least five unique chemical entities should be preferred. 2. Require appropriate ICD-9 on all prescriptions for agents within this class. 3. Place quantity limits on all agents in the class. 4. Allow only two agents at a time unless switching agents due to therapeutic failure or the patient is refractory to dual therapy. 5. Allow continuation of therapy for non preferred single source branded products via a 90 day look back. 6. All products in the category should have a tier 1 copay regardless of preferred or non preferred status. 7. For any new chemical entity in the Antipsychotics: Atypical class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Abilify® clozapine Fanapt™ Fazaclo® Geodon® risperidone Saphris® Seroquel® Seroquel® XR Zyprexa® **Non Preferred** Agent (s) Clozaril® Invega® Risperdal®

Description of Recommendation	Final Decision (s)

Atypical Antipsychotics Clinical Criteria
Preferred Atypical Antipsychotics will be allowed for approvable diagnoses only.
 	
*Non preferred Atypical Antipsychotics will be approved after a 2-week trial of ONE preferred Atypical Antipsychotic at an appropriate dose. If Invega® is selected as non preferred, approval will be granted if one of the following is true:
• Trial and failure of risperidone ; OR
• Patient has hepatic impairment evident by elevated liver enzymes or a diagnosis suggestive of hepatic impairment
**For a diagnosis not specifically mentioned above, an atypical may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.
 	
Major Depressive Disorder (MDD) Criteria:
Atypical Antipsychotics will be approved for MDD as adjunct therapy ONLY. Atypicals will be approved if any ONE of the following is true:
• An adequate trial (4 weeks) of at least one agent in two of the following classes of antidepressants (unless contraindicated or intolerant to):
  • Selective Serotonins Reuptake Inhibitor (SSRIs)
  • Serotonin-Norepinephrine Reuptake Inhibitor (SNRIs)
  • New Generation Antidepressants
  • Tricyclic antidepressants (TCAs); OR
• A diagnosis of Major Depressive Disorder (MDD) with psychotic features.
	Atypical Antipsychotics Clinical Criteria
	Preferred Atypical Antipsychotics will be allowed for approvable diagnoses only.
	
	*Non preferred Atypical Antipsychotics will be approved after a 2-week trial of ONE preferred Atypical Antipsychotic at an appropriate dose. Invega® will be approved if one of the following is true:
	• Trial and failure of risperidone ; OR
	• Patient has hepatic impairment evident by elevated liver enzymes or a diagnosis suggestive of hepatic impairment
	**For a diagnosis not specifically mentioned above, an atypical may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.
	
	Major Depressive Disorder (MDD) Criteria:
	Atypical Antipsychotics will be approved for MDD as adjunct therapy ONLY. Atypicals will be approved if any ONE of the following is true:
	• An adequate trial (4 weeks) of at least one agent in two of the following classes of antidepressants (unless contraindicated or intolerant to):
	  • Selective Serotonins Reuptake Inhibitor (SSRIs)
	  • Serotonin-Norepinephrine Reuptake Inhibitor (SNRIs)
	  • New Generation Antidepressants
	  • Tricyclic antidepressants (TCAs); OR
	• A diagnosis of Major Depressive Disorder (MDD) with psychotic features.

Multiple Agents Criteria:
Patients who are on more than 2 Atypical Antipsychotic agents will require PA. Approval will be granted for the following reasons:

- A maximum of 2 months to allow patients to taper to dual therapy.
- Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.

Proposed Quantity Limits:

Drug	Strength	Per Day Count
Abilify®	All Strengths	1 per day (30 mg per day max)
Abilify Discmelt®	All Strengths	2 per day (30 mg per day max)
Abilify® oral solution	1mg/mL	25 mL per day (30 mg per day max)
Clozaril® / clozapine	12.5 mg	3 per day (900 mg per day max)
	25 mg	3 per day (900 mg per day max)
	50 mg	3 per day (900 mg per day max)
	100 mg	9 per day (900 mg per day max)
	200 mg	4 per day (900 mg per day max)
Fanapt™	All Strengths	2 per day (24 mg per day max)
FazaClo ODT®	12.5 mg	3 per day (900 mg per day max)
	25 mg	3 per day (900 mg per day max)
	50 mg	3 per day (900 mg per day max)
	100 mg	9 per day (900 mg per day max)
Geodon®	All Strengths	2 per day (160 mg per day max)
Invega®	1.5 mg	1 per day (12 mg per day max)
	3 mg	1 per day (12 mg per day max)
	6 mg	2 per day (12 mg per day max)
	9 mg	1 per day (12 mg per day max)
Risperdal® / risperidone	All Strengths	2 per day (8 mg per day max)
Risperdal® / risperidone oral solution	1 mg/mL	8 mL per day (8 mg per day max)
Saphris®	All Strengths	2 per day (20 mg per day max)
Seroquel®	25 mg	3 per day (800 mg per day max)
	50 mg	3 per day (800 mg per day max)
	100 mg	3 per day (800 mg per day max)
	200 mg	3 per day (800 mg per day max)
	300 mg	2 per day (800 mg per day max)
	400 mg	2 per day (800 mg per day max)
Seroquel XR®	50 mg	2 per day (800 mg per day max)
	150 mg	1 per day (800 mg per day max)
	200 mg	1 per day (800 mg per day max)
	300 mg	2 per day (800 mg per day max)
	400 mg	2 per day (800 mg per day max)
Zyprexa® / Zyprexa Zydis®	All Strengths	1 per day

Multiple Agents Criteria:
Patients who are on more than 2 Atypical Antipsychotic agents will require PA. Approval will be granted for the following reasons:

- A maximum of 2 months to allow patients to taper to dual therapy.
- Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.

Quantity Limits:

Drug	Strength	Per Day Count
Abilify®	All Strengths	1 per day (30 mg per day max)
Abilify Discmelt®	All Strengths	2 per day (30 mg per day max)
Abilify® oral solution	1mg/mL	25 mL per day (30 mg per day max)
Clozaril® / clozapine	12.5 mg	3 per day (900 mg per day max)
	25 mg	3 per day (900 mg per day max)
	50 mg	3 per day (900 mg per day max)
	100 mg	9 per day (900 mg per day max)
	200 mg	4 per day (900 mg per day max)
Fanapt™	All Strengths	2 per day (24 mg per day max)
FazaClo ODT®	12.5 mg	3 per day (900 mg per day max)
	25 mg	3 per day (900 mg per day max)
	50 mg	3 per day (900 mg per day max)
	100 mg	9 per day (900 mg per day max)
Geodon®	All Strengths	2 per day (160 mg per day max)
Invega®	1.5 mg	1 per day (12 mg per day max)
	3 mg	1 per day (12 mg per day max)
	6 mg	2 per day (12 mg per day max)
	9 mg	1 per day (12 mg per day max)
Risperdal® / risperidone	All Strengths	2 per day (8 mg per day max)
Risperdal® / risperidone oral solution	1 mg/mL	8 mL per day (8 mg per day max)
Saphris®	All Strengths	2 per day (20 mg per day max)
Seroquel®	25 mg	3 per day (800 mg per day max)
	50 mg	3 per day (800 mg per day max)
	100 mg	3 per day (800 mg per day max)
	200 mg	3 per day (800 mg per day max)
	300 mg	2 per day (800 mg per day max)
	400 mg	2 per day (800 mg per day max)
Seroquel XR®	50 mg	2 per day (800 mg per day max)
	150 mg	1 per day (800 mg per day max)
	200 mg	1 per day (800 mg per day max)
	300 mg	2 per day (800 mg per day max)
	400 mg	2 per day (800 mg per day max)
Zyprexa® / Zyprexa Zydis®	All Strengths	1 per day

Description of Recommendation	Final Decision (s)
Injectable Antipsychotics 1. DMS to select preferred agent(s) based on economic evaluation. Generic formulations of first generation injectable antipsychotics should be preferred. Additionally, two unique second generation injectable antipsychotics, one of which should have a duration of action of 2 weeks or longer, should be preferred. 2. Require appropriate ICD-9 on all prescriptions for agents within this class. 3. Allow only two agents at a time unless switching agents due to therapeutic failure or the patient is refractory to dual therapy. 4. Allow continuation of therapy for non preferred single source branded products via a 90 day look back. 5. All products in the category should have a tier 1 copay regardless of preferred or non preferred status. 6. For any new chemical entity in the Injectable Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) chlorpromazine Abilify® fluphenazine decanoate Geodon® haloperidol decanoate Invega® Sustenna™ Risperdal® Consta® Zyprexa® **Non Preferred** Agent (s) Haldol® Decanoate Zyprexa® Relprevv
Injectable Antipsychotics Clinical Criteria Preferred Injectable Antipsychotics will be allowed for approvable diagnoses only. *Non preferred Injectable Antipsychotics will be approved after a 2-week trial of ONE preferred Antipsychotic (oral or parenteral) at an appropriate dose. If Invega® Sustenna™ is selected as non preferred, approval will be granted if one of the following is true: • Trial and failure of risperidone ; OR • Patient has hepatic impairment evident by elevated liver enzymes or a diagnosis suggestive of hepatic impairment **For a diagnosis not specifically mentioned above, an injectable antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.	**Injectable Antipsychotics Clinical Criteria** Preferred Injectable Antipsychotics will be allowed for approvable diagnoses only. *Non preferred Injectable Antipsychotics will be approved after a 2-week trial of ONE preferred Antipsychotic (oral or parenteral) at an appropriate dose. **For a diagnosis not specifically mentioned above, an injectable antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

Multiple Therapy Criteria:
Patients who are on more than two Atypical Antipsychotic agents will require PA. Approval will be granted for the following reasons:

- A maximum of 2 months to allow patients to taper to dual therapy.
- Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose if each agent.

Proposed Quantity Limits:

Drug	Strength	Per Day Count
Abilify®	9.7 mg/1.3 mL	1.3 mL per day
fluphenazine decanoate	25 mg/mL	4 mL per month
haloperidol decanoate / Haldol® Decanoate	50 mg/mL	1 mL per month
	100 mg/mL	2 mL per month
Zyprexa®	10 mg	30 mg per RX
Zyprexa® Relprevv	210 mg	210 mg every 2 weeks
	300 mg	300 mg every 2 weeks
	405 mg	405 mg every 4 weeks
Invega® Sustenna™	39 mg/0.25 mL	0.25 mL per month
	78 mg/0.5 mL	0.5 mL per month
	117 mg/0.75 mL	0.75 mL per month
	156 mg/1 mL	1 mL per month
	234 mg/1.5mL	1.5 mL per month
Risperdal® Consta®	12.5 mg	12.5 mg every 2 weeks
	25 mg	25 mg every 2 weeks
	37.5 mg	37.5 mg every 2 weeks
	50 mg	50 mg every 2 weeks
Geodon®	20 mg	40 mg per RX

Atypical Antipsychotic and SSRI Combinations

1. DMS to select preferred agent(s) based on economic evaluation.
2. Require prior authorization and quantity limits for agents in this class.
3. Require prior authorization if this product is being used with more than one other atypical antipsychotic unless switching agents due to therapeutic failure or the patient is refractory to dual atypical antipsychotic therapy.
4. Allow continuation of therapy for non preferred single source branded products via a 90 day look back.
5. For any new chemical entity in the Atypical Antipsychotic and SSRI Combination class, require a PA until reviewed by the P&T Advisory Committee.

Multiple Therapy Criteria:
Patients who are on more than two Atypical Antipsychotic agents will require PA. Approval will be granted for the following reasons:

- A maximum of 2 months to allow patients to taper to dual therapy.
- Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose if each agent.

Quantity Limits:

Drug	Strength	Per Day Count
Abilify®	9.7 mg/1.3 mL	1.3 mL per day
fluphenazine decanoate	25 mg/mL	4 mL per month
haloperidol decanoate / Haldol® Decanoate	50 mg/mL	1 mL per month
	100 mg/mL	2 mL per month
Zyprexa®	10 mg	30 mg per RX
Zyprexa® Relprevv	210 mg	210 mg every 2 weeks
	300 mg	300 mg every 2 weeks
	405 mg	405 mg every 4 weeks
Invega® Sustenna™	39 mg/0.25 mL	0.25 mL per month
	78 mg/0.5 mL	0.5 mL per month
	117 mg/0.75 mL	0.75 mL per month
	156 mg/1 mL	1 mL per month
	234 mg/1.5mL	1.5 mL per month
Risperdal® Consta®	12.5 mg	12.5 mg every 2 weeks
	25 mg	25 mg every 2 weeks
	37.5 mg	37.5 mg every 2 weeks
	50 mg	50 mg every 2 weeks
Geodon®	20 mg	40 mg per RX

Selected **Preferred** Agent (s)
Symbyax®

Non Preferred Agent (s)
N/A

<table>
<tr><th>Description of Recommendation</th><th>Final Decision (s)</th></tr>
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<u>Atypical Antipsychotics and SSRI Combinations Clinical Criteria</u>
Symbyax® will be approved if BOTH of the following are true:
• Diagnosis of depressive episodes associated with bipolar disorder; AND,
• Trial and failure of ONE of the following:
o Lithium; OR
o Lamotrigine; OR
o Bupropion; OR
o Paroxetine.

**For a diagnosis not specifically mentioned above, Symbyax® may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

Multiple Therapy Criteria:
Patients who are on more than 2 Atypical Antipsychotic agents will require PA. Approval will be granted for the following reasons:
• A maximum of 2 months to allow patients to taper to dual therapy.
• Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.

Proposed Quantity Limits:

<table>
<tr><th>Drug</th><th>Strength</th><th>Per Day Count</th></tr>
<tr><td>Symbyax®</td><td>All Strengths</td><td>1 per day</td></tr>
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<td>
<u>Atypical Antipsychotics and SSRI Combinations Clinical Criteria</u>
Symbyax® will be approved if BOTH of the following are true:
• Diagnosis of depressive episodes associated with bipolar disorder; AND,
• Trial and failure of ONE of the following:
o Lithium; OR
o Lamotrigine; OR
o Bupropion; OR
o Paroxetine.

**For a diagnosis not specifically mentioned above, Symbyax® may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

Multiple Therapy Criteria:
Patients who are on more than 2 Atypical Antipsychotic agents will require PA. Approval will be granted for the following reasons:
• A maximum of 2 months to allow patients to taper to dual therapy.
• Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.

Quantity Limits:

<table>
<tr><th>Drug</th><th>Strength</th><th>Per Day Count</th></tr>
<tr><td>Symbyax®</td><td>All Strengths</td><td>1 per day</td></tr>
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Description of Recommendation	Final Decision (s)
First Generation Anticonvulsants 1. DMS to select preferred agent (s) based on economic evaluation; however, at least all generic products should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. Require therapeutic failure of one preferred agent prior to approval of a non-preferred agent. 4. Non preferred products will continue to require a tier 1 co-payment for generics and a tier 2 co-payment for branded products. 5. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 6. For any new chemical entity in the Anticonvulsants: First Generation class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Celontin® clonazepam DiaStat® divalproex delayed-release divalproex sodium extended-release ethosuximide mephobarbital Peganone® phenobarbital Phenytek® phenytoin primidone valproic acid **Non Preferred** Agent (s) Depakene® Depakote® Depakote ER® diazepam rectal gel Dilantin® Klonopin® Mebaral® Stavzor™ Zarontin®
Bisphosphonates 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one bisphosphonate should be preferred. 2. Agents not selected as will be considered non preferred and require PA. 3. Continue quantity limits based on maximum recommended dose. 4. Once monthly formulations will be approved for patients with poor compliance utilizing once weekly formulations only. 5. For any new chemical entity in the Bisphosphonate class, require a PA until reviewed by the PTAC.	Selected **Preferred** Agent (s) alendronate **Non Preferred** Agent (s) Actonel® Actonel with Calcium® Atelvia® Boniva® Didronel® etidronate Fosamax® Fosamax Plus D™ Reclast® Skelid®