



Recommended changes to limitations of drugs on the PDL

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Newer Diabetics – DPP-4 Inhibitor Products

Ingredient	Label Name	Generic Available	Current PDL Status
Alogliptin benzoate	Nesina®	Yes	Non-Preferred
Linagliptin	Tradjenta®	No	Preferred
Saxagliptin HCl	Onglyza®	No	Non-Preferred
Sitagliptin phosphate	Januvia®	No	Non-Preferred

SGLT-2 Inhibitor Products

Ingredient	Label Name	Generic Available	Current PDL Status
Canagliflozin	Invokana®	No	Non-Preferred
Dapagliflozin propanediol	Farxiga®	No	Preferred
Empagliflozin	Jardiance®	No	Not Reviewed

Newer Diabetics – GLP-1 Analogs Products

Ingredient	Label Name	Generic Available	Current PDL Status
Abiglutide	Tanzeum™	No	Not Reviewed
Dulaglutide	Trulicity®	No	Not Reviewed
Exenatide	Byetta®	No	Preferred
Exenatide XR	Bydureon®	No	Non-Preferred
Liraglutide	Victoza®	No	Non-Preferred

Amylin Agonist Products

Ingredient	Label Name	Generic Available	Current PDL Status
Pramlintide acetate	SymlinPen®	No	Non-Preferred



Newer Diabetics

- Current Limitations:
 - No TIP for Amylin Agonist products (P&T Motion from 9/24/2014)
 - Must step through one preferred product before a non-preferred will be authorized
 - Prior authorization required

Newer Diabetics

- Prior Authorization Criteria
 - DPP-4 Inhibitors and SGLT-2 Inhibitors
 - Diagnosis of type 2 diabetes mellitus
 - Tried and failed metformin, currently taking, or contraindicated for use
 - Dosing within recommended dosing limits

Newer Diabetics

- Prior Authorization Criteria continued
 - GLP-1 Analogs
 - Diagnosis of type 2 diabetes mellitus
 - Tried and failed metformin, currently taking, or contraindicated for use
 - Dosing must be within recommended maximum limits
 - None of the following:
 - History of medullary thyroid carcinoma (MTC) (except Byetta)
 - Multiple endocrine neoplasia syndrome type 2 (MEN2) (except Byetta)
 - History of pancreatitis
 - Gastroparesis
 - Severe renal impairment or end-stage renal disease (ESRD) for Byetta or Bydureon
 - Concomitant insulin use
 - Basal insulin – Bydureon, Trulicity
 - Prandial insulin – Bydureon, Byetta, Tanzeum, Victoza



Newer Diabetics

- Prior Authorization Criteria continued
 - Amylin Agonist
 - Diagnosis
 - Type 1 diabetes mellitus
 - » Maximum dose 60 µg per major meal
 - Type 2 diabetes mellitus
 - » Maximum dose 120 µg per major meal
 - Must be used with concomitant prandial insulin
 - None of the following:
 - HbA1c >9%
 - Gastroparesis
 - Risk of hypoglycemia; poor awareness of hypoglycemia, severe hypoglycemia in last 6 months
 - Poor compliance with insulin doses, glucose monitoring, or clinic visits
 - Prescriber will monitor weekly until Symlin and insulin doses stable

Diabetes Pharmacological Treatment Guidelines

American Diabetes Association (ADA) 2016 recommendations – Standards of Medical Care in Diabetes (Diabetes Care 2016 Jan; 39 Supplement 1:S52-S59)

Pharmacological Therapy for Type 1 Diabetes

1. Insulin Therapy
 - A. Multiple-dose insulin (3-4 injections per day of basal and prandial insulin) or continuous SQ insulin infusion
 - B. Insulin analogs to reduce hypoglycemia risk
2. Pramlintide
3. Pancreas and Islet Cell Transplantation

Pharmacological Therapy for Type 2 Diabetes

1. Initial Therapy
 - A. Metformin is preferred, unless contraindicated or not tolerated
 - B. Consider insulin therapy (with or without additional agents) in newly diagnosed and markedly symptomatic and/or elevated blood glucose or HbA1c levels
2. Combination Therapy
 - A. If noninsulin monotherapy at max tolerated dose does not achieve or maintain HbA1c target over 3 months, add second oral agent, a GLP-1, or basal insulin
3. Insulin Therapy
 - A. If not achieving glycemic goals, insulin therapy should not be delayed



Newer Diabetics

- Recommendations:
 - Continue no TIP for Amylin Agonist products as previously recommended by P&T
 - Remove PA criteria for this class
 - Add EA code to Amylin for type I diabetes
 - Must step through all preferred drugs with same indication within the same subclass before a non-preferred will be authorized
 - Combination products may be used when dual treatment is needed. Single ingredient products should not be used if a combination product with that same ingredient is used.



Stakeholder Comments?

- Motion: “I move the Medicaid Fee-For-Service Program implement the limitations for the Newer Diabetics drug class listed on slide 9 as amended ”

Asthma Controller or COPD – Inhaled Corticosteroid (ICS) Products

Ingredient	Label Name	Generic Available	Current PDL Status
Beclomethasone dipropionate	QVAR®	No	Preferred
Budesonide	Pulmicort Respules®	Yes	Generic Preferred
	Pulmicort Flexhaler®	No	Non-Preferred
Ciclesonide	Alvesco®	No	Non-Preferred
Flunisolide	AeroSpan®	No	Non-Preferred
Fluticasone furoate	Arnuity™ Ellipta®	No	Not Reviewed
Fluticasone propionate	Flovent® Diskus®, Flovent® HFA	No	Preferred
Mometasone furoate	Asmanex® Twisthaler®, Asmanex® HFA	No	Non-Preferred



Asthma Controller or COPD – Long-Acting Beta-Agonist (LABA) Products

Ingredient	Label Name	Generic Available	Current PDL Status
Aformoterol tartrate	Brovana®	No	Non-Preferred
Formoterol fumarate	Foradil® Aerolizer®, Perforomist®	No	Non-Preferred
Indacaterol maleate	Arcapta™ Neohaler™	No	Non-Preferred
Olodaterol HCl	Striverdi® Respimat®	No	Not Reviewed
Salmeterol xinaforate	Serevent®	No	Preferred

Asthma Controller or COPD – Long-Acting Muscarinic Antagonist (LAMA) Products

Ingredient	Label Name	Generic Available	Current PDL Status
Acclidinium bromide	Tudorza® Pressair®	No	Non-Preferred
Glycopyrrolate bromide	Seebri™ Neohaler®	No	Not Reviewed
Tiotropium bromide	Spiriva® HandiHaler®, Spiriva® Respimat®	No	Preferred
Umeclidinium bromide	Incruse® Ellipta®	No	Not Reviewed

Asthma Controller or COPD – ICS/LABA Combination Products

Ingredient	Label Name	Generic Available	Current PDL Status
Budesonide/ formoterol	Symbicort®	No	Non-Preferred
Fluticasone furoate/ vilanterol	Breo® Ellipta®	No	Preferred
Fluticasone/ salmeterol	Advair® Diskus, Advair® HFA	No	Preferred
Mometasone furoate/ formoterol	Dulera®	No	Non-preferred



Asthma Controller or COPD – LABA/LAMA Combination Products

Ingredient	Label Name	Generic Available	Current PDL Status
Formoterol formoterol/ glycopyrrolate	Bevespi Aerosphere™	No	Not Reviewed
Indacaterol/ glycopyrrolate bromide	Utibron™ Neohaler®	No	Not Reviewed
Olodaterol HCl/ tiotropium bromide	Stiolto® Respimat®	No	Not Reviewed
Vilanterol/ umeclidinium bromide	Anoro® Ellipta®	No	Preferred



Asthma Controller or COPD – Phosphodiesterase-4 (PDE-4) Inhibitors

Ingredient	Label Name	Generic Available	Current PDL Status
Roflumilast	Daliresp®	No	Preferred



Asthma Controller or COPD – Leukotriene Modifier Products

Ingredient	Label Name	Generic Available	Current PDL Status
Montelukast sodium	Singulair®	Yes	Generic Preferred
Zafirlukast	Accolate®	Yes	Generic Preferred
Zileuton	Zyflo®, Zyflo CR®	No	Non-Preferred

Asthma Controller or COPD

- Current Limitations:
 - Must step through one preferred product within subclass before a non-preferred in that subclass will be authorized
 - EA criteria
 - LABA: EA for diagnosis of COPD
 - LAMA: EA for diagnosis of COPD; (except Spiriva Respimat indicated for Asthma & COPD)
 - ICS/LABA: EA for diagnosis of asthma for Dulera only
 - LABA/LAMA: EA for diagnosis of COPD
 - PDE-4: EA for diagnosis of COPD
- Recommendation:
 - Must step through all preferred drugs within subclass with same indication before a non-preferred in that subclass will be authorized
 - Continue EA for diagnosis



Stakeholder Comments?

- Motion: “I move the Medicaid Fee-For-Service Program implement the limitations for the asthma controller or COPD drug class listed on slide 18 as recommended.

Asthma Quick Relief – Short-Acting Beta-Agonist (SABA) Products

Ingredient	Label Name	Generic Available	Current PDL Status
Albuterol sulfate	Accuneb®	Yes	Generic Preferred
	ProAir® HFA	No	Preferred
	ProAir Respiclick®, Proventil® HFA, Ventolin® HFA	No	Non-Preferred
Levalbuterol HCl	Xopenex® neb	Yes	Non-Preferred
Levalbuterol tartrate	Xopenex HFA®	No	Non-Preferred

Asthma Quick Relief

- Current Limitations:
 - Must step through one preferred product with same type of drug delivery system before a non-preferred will be authorized
- Recommendations:
 - Must step through all preferred drugs with same route of administration before a non-preferred will be authorized



Stakeholder Comments?

- Motion: “I move the Medicaid Fee-For-Service Program implement the limitations for the Asthma Quick Relief drug class listed on slide 21 as recommended

Newer Sedative Hypnotics Products

Ingredient	Label Name	Generic Available	Current PDL Status
Eszopiclone	Lunesta®	Yes	Non-Preferred
Remelteon	Rozerem®	No	Preferred
Suvorexant	Belsomra®	No	Not Reviewed
Zaleplon	Sonata®	Yes	Generic Preferred
Zolpidem tartrate	Ambien	Yes	Preferred
	Intermezzo SL tab	Yes	Non-preferred
	Edluar SL tab	No	Non-preferred
	Zolpimist oral spray	No	Non-preferred
Zolpidem tartrate controlled-release	Ambien CR	Yes	Not Preferred



Newer Sedative Hypnotics

- Current Limitations:
 - Under 18 years of age require a Second Opinion Network (SON) consultation
 - Age 18 years and older
 - Maximum daily dose limits per FDA labeling
 - Must step through one preferred product before a non-preferred will be authorized
 - Allow 1 month of #30 tablets per 30 day supply; then use EA for diagnosis of insomnia for #10 tablet for 30 day supply or pharmacy can initiate prior authorization
 - Zolpidem immediate-release may allow additional 3 months of #30 tablets for 30 day supply
 - All others allow 1 additional month of #30 tablets per 30 days supply
 - PA to review for psychiatric diagnosis
 - Rozerem Only
 - Allow 3 months of #30 tablets per 30 day supply then pharmacy can initiate prior authorization
 - Allow 1 additional month of #30 tablets for 30 day supply
 - PA to review for psychiatric diagnosis



Newer Sedative Hypnotics

American Academy of Sleep Medicine (AASM) – Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults (J Clin Sleep Med 2008 Oct 15;4(5)487)

- Treatment goals
 - Improve sleep quality, quantity and improve insomnia related daytime impairments
- Psychological and behavioral interventions
 - Sleep hygiene, cognitive behavioral therapy for insomnia
- Pharmacological treatment
 - Short term hypnotic treatment supplemented with behavioral or cognitive therapies
 - Long-term treatment may be indicated for severe or refractory insomnia or chronic comorbid illness



Newer Sedative Hypnotics

- Recommendation
 - Continue second opinion for under 18 years of age
 - Must step through all preferred drugs before a non-preferred will be authorized
 - Remove prior authorization criteria for adults
 - Quantity limit of one dose per day



Stakeholder Comments?

- Motion: “I move the Medicaid Fee-For-Service Program implement the limitations for the Newer Sedative Hypnotic drug class listed on slide 26 as recommended

Antidepressant Duplication Products

SSRI	NaSSA	NDRI	SARI	SNRI
<ul style="list-style-type: none"> • Citalopram (Celexa) • Escitalopram (Lexapro) • Fluoxetine (Prozac, Sarafem) • Fluvoxamine (Luvox) • Paroxetine HCl (Paxil) • Paroxetine mesylate (Pexeva) • Sertraline (Zoloft) • Vilazodone (Viibryd) • Vortioxetine (Trintellix) 	<ul style="list-style-type: none"> • Mirtazapine (Remeron) 	<ul style="list-style-type: none"> • Bupropion HCl (Forfivo XL, Wellbutrin, Wellbutrin SR, Wellbutrin XL) • Bupropion HBr (Aplenzin) 	<ul style="list-style-type: none"> • nefazadone 	<ul style="list-style-type: none"> • Duloxetine (Cymbalta, Irenka) • Desvenlafaxine (Pristiq, Khedezla) • Venlafaxine (Effexor, Effexor XR, Venlafaxine XR tablet)



Antidepressant Duplication Combinations

Class	SSRI	NaSSA	NDRI	SARI	SNRI
SSRI (Selective Serotonin Reuptake Inhibitor)	PA			PA	PA
NaSSA (Noradrenergic & Specific Serotonergic Antidepressant)		PA		PA	
NDRI (Norepinephrine/Dopamine Reuptake Inhibitor)			PA		
SARI (Serotonin Antagonist Reuptake Inhibitor)	PA	PA		PA	
SNRI (Serotonin Norepinephrine Reuptake Inhibitor)	PA				PA



Antidepressant Duplication

- Current Limitations:
 - System allows 2 months of duplication prior to the rejection
 - Pharmacy initiates the prior authorization
 - 2 month continuation fill while requesting additional information from prescriber(s)

Antidepressant Duplication

- Current Criteria
 - Age 18 years and older
 - Justification of medical necessity for use of combination of antidepressants
 - Severity of condition for which combination of medication is prescribed
 - Tried and failed all medications monotherapy and/or approved combinations
 - Under the age of 18 years
 - Second Opinion Network (SON) consultation



Serotonin Syndrome

- Mild to potentially life threatening condition
 - Serotonin toxicity caused by therapeutic medication use, inadvertent interactions between drugs, and intentional self-poisoning
- Majority of cases present within 24 hours, most within 6 hours after change in dose or initiation of a drug



Antidepressant Duplication

- Recommendation:
 - For under the age of 18, process remains unchanged
 - For age 18 years and older, remove prior authorization for antidepressant duplication
 - Allow claim to pay, include notification of two or more antidepressants and encourage pharmacist to counsel patient of potential increased risk of serotonin syndrome

Stakeholder Comments?

- Motion: “I move the Medicaid Fee-For-Service Program implement the limitations for the antidepressant duplication listed on slide 33 as recommended