Beneficiary Advisory Panel Handout

Uniform Formulary Decisions

25 September 2014

Purpose: The purpose of this handout is to provide the BAP members with a reference document for the clinical effective presentation for each Uniform Formulary (UF) decision.

NEW DRUG REVIEW

Class: Non-Insulin Diabetes Agents Subclass: Glucagon-Like Peptide Receptor Agonist (GLP1RA) – albilutide injection (Tanzeum)

Recommended for Uniform Formulary: albilutide (Tanzeum)

Current Uniform Formulary Agents: Exenatide twice daily (Byetta), Exenatide weekly (Bydureon), Liraglutide (Victoza)

Non-Formulary Agents: None

Existing prior authorization criteria requires a trial of metformin or sulfonylurea prior to the use of any non-insulin diabetes drug subclasses (except for alpha-glucosidase inhibitors and meglitinides).

Prior Authorization Criteria: Coverage is approved for albiglutide (Tanzeum); a trial of metformin or sulfonylurea is NOT required if:

1. Patient has experienced any of the following adverse drug reactions on:
    a. Metformin
        i. Impaired renal function precluding treatment with metformin
        ii. History of lactic acidosis
    b. Hypoglycemia requiring medical treatment
2. Patient had an inadequate response to metformin or a sulfonylurea
3. Patient has a contraindication to metformin or a sulfonylurea

Recommended Implementation Date: 90 days

Total Number of patients affected: 4

Class: Attention Deficit Hyperactive Disorder (ADHD), Subclass: Stimulants – methylphenidate extended release (ER) oral suspension (Quillivant XR)

Recommended for Non-Formulary: methylphenidate ER suspension (Quillivant XR)

Uniform Formulary Agents: mixed amphetamine salts (Adderall XR), methylphenidate ER (Concerta), methylphenidate LA (Ritalin LA), Metadate CD, Metadate ER, Methylin, Methylin ER; SR (Ritalin SR)

Non-Formulary Agents: dexamethylphenidate ER (Focalin XR), lisdexamphetamine ER (Vyvanse), methylphenidate (Daytrana)

Recommended Implementation Date: 90 days

Total Number of patients affected: 994

DRUG CLASS REVIEW

Class: Targeted Immunomodulatory Biologics (TIBs)

Figure 1: Drugs in the Class and FDA indications.

TIBs Class Definition / FDA Indications / Other uses

Generic	Brand	MoA	Route of Admin.	Other	Rheum				Derm	Gastro	
					RA	JIA	AS	PsA	Plaque Psoriasis	Crohn's	UC
Adalimumab	Humira	TNF	SQ		X	≥ 4	X	X	X	X	X
Certolizumab	Cimzia	TNF	SQ		X		X	X		X	
Etanercept	Enbrel	TNF	SQ		X	≥ 2	X	X	X		
Golimumab	Simponi	TNF	SQ	*w/ MTX	X*		X	X			X
Abatacept	Orencia	CTLA4	SQ		X						
Tocilizumab	Actemra	IL6	SQ	DMARD-IR	X						
Tofacitinib	Xeljanz	JAK	PO	MTX-IR	X						
Anakinra	Kineret	IL1	SQ	NOMID, Gout	X						
Ustekinumab	Stelara	IL12	SQ					X	X		
Apremilast	Otezla	PDE-4	PO				FDA	X	FDA		
Not available for Tricare outpatient pharmacy benefit											
Abatacept	Orencia	CTLA 4	IV		X	≥ 6					
Golimumab	Simponi	TNF	IV		X						
Tocilizumab	Actemra	IL6	IV		X	≥ 2					

RA = rheumatoid arthritis; JIA = juvenile idiopathic arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; UC = ulcerative colitis; NOMID = neonatal onset multisystem inflammatory disease

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Uniform Formulary Agents (step preferred): adalimumab (Humira)

Uniform Formulary Agents non-preferred: apremilast (Otezla), golimumab (Simponi), tofacitinib (Xeljanz), and ustekinumab (Stelara)

Non-Formulary Agents non-preferred: abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel) and tocilizumab (Actemra)

Step therapy applies to new users of TIBs. All new users of the non-preferred TIBs [abatacept (Orencia), anakinra (Kineret), apremilast (Otezla), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), tocilizumab (Actemra), tofacitinib (Xeljanz), and ustekinumab (Stelara)], require a trial of adalimumab (Humira) before the non-step preferred drugs.

A trial of Humira is not required if:

- Contraindications exist to Humira
- The patient has had an inadequate response to Humira, and requires a different anti-Tumor Necrosis Factor (TNF) biologic or a non-TNF biologic
- The patient has experienced adverse reactions to Humira which are not expected to occur with the requested non-preferred TIB
- There is no formulary alternative for the following:
    - Enbrel: Patient is a child younger than four years of age or the patient has hepatitis C virus
    - Non-TNF TIB (Orencia, Actemra, Xeljanz, Kineret, Stelara, and Otezla): Patient has symptomatic chronic heart failure
    - Actemra, Orencia or Simponi: Patient has been stable on an intravenous formulation, with continuous use in the past three months and needs to transition to the subcutaneous formulation

Manual Prior Authorization for all users of Humira or a non-preferred TIB is required. Coverage of the TIBs is only allowed for the FDA-approved indication and coverage is not approved for concomitant use of the TIBs with other biologic agents.

Recommended Implementation Date: 90 days

Total Number of patients affected: 1,929

Meeting	Drug Class	Non-formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Step Therapy
				MTF	Retail	Mail Order		
August 2014	**Target Immunomodulatory Biologics**	Abatacept (Orencia) Anakinra (Kineret) Certolizumab (Cimzia) Etanercept (Enbrel) Tocilizumab (Actemra)	1,929	499	736	694	90 days	Must try adalimumab (Humira) first in all new users
	GLP1RA	None (Tanzeum recommended for UF, but step therapy applies)	4	0	3	1	30 days	Must try metformin or sulfonylurea prior to the use of any non-insulin diabetes drug subclasses (GLP1RA)
	ADHD	Quillivant XR	994	85	883	26	90 days	