

**State and Public School Life and Health Insurance
Board Clinical and Fiscal Drug Utilization and
Evaluation Committee
Minutes
April 4, 2011**

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Monday, April 4, 2011 at 1:00 p.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

Members present:

Dr. William Golden
Dr. Joe Stallings
Kat Neill
Larry Dickerson/Proxy
Dr. Hank Simmons
Mark McGrew

Members absent:

Robert Watson
Matthew Hadley

Jason Lee, Executive Director, Employee Benefits Division of DFA.

OTHERS PRESENT

Jill Johnson, UAMS College of Pharmacy/EBRx; Connie Bennett, Informed Rx; Doug Shackelford, Lori Eden, Amy Tustison, Sherri Saxby, Kristie Cox, Sherry Bryant; Cathy Harris, EBD; Barbara Melugin, Health Advantage; Bridget Johnson, Pfizer, Wayne Whitley, Ronda Walthall, AHTD; Dwight Davis, UAMS; Julie Ryba; Shonda Rocke, Informed Rx; Bryan Meldrum, Novasys; Frances Baumen, Novo Nordisk; Warren Tyes, Merck; Mark DeClark, Lilly; Charlene Kaiser, Amgen; Julie Huff, Takeda

CALL TO ORDER

Meeting was called to order by Dr. Golden.

APPROVAL OF MINUTES

The motion was made by Dr Golden to approve the February 7, 2011 minutes. Minutes were approved by consensus.

DIABETIC MEDICATION DISCUSSION by Jill Johnson

Dr. Golden explained that the Board requested that the committee resubmit their recommendation for Pioglitazone with a step therapy criteria, and create a step therapy criteria for Pramlintide (Symlin, SymlinPen) before the Board will entertain the recommendation to exclude Pramlintide from coverage.

Dr. Golden said the Board was interested in option 2 for Exenatide (Byetta), Liraglutide (Victoza) and Sitagliptin (Janumet) Saxagliptin, (Onglyza, Kombiglyze XR) but decline to make a decision until the DUEC return with a viable mechanism on how to implement option 2

1. TZDs (rosiglitazone, pioglitazone), (Avandia, Avandaryl, Avandamet, Actos, Actoplus Met)

- Restrict the access to rosiglitazone. Stop covering rosiglitazone (Avandia, Avandamet, and Avandaryl) effective July 1, 2011. (This item approved by the Board in previous meeting.)
- No pioglitazone (Actos) without metformin (at a near maximum daily dose-2000mg daily) or a contraindication to metformin.

Johnson presented the proposed step therapy guidelines for pioglitazone (Actos and Actos-containing products including pioglitazone-glimepiride, pioglitazone-metformin, and future combinations).

STEP THERAPY:

- a. Patients taking metformin for the past 4 of 5 months and taking a sulfonylurea for the past 4 of 5 months may have pioglitazone. If the 80% adherence rate is not maintained, pioglitazone access will be denied at the point of sale.
- b. Patients must adhere to at least 4 of the previous 5 months of metformin + sulfonylurea and fail to meet HbA1C goal prior to gaining access to pioglitazone-metformin (Actoplus Met) combination therapy.
- c. Patients must adhere to at least 4 months of metformin monotherapy and an additional 4 months of metformin + sulfonylurea and/or fail to meet HbA1C goal prior to gaining access to pioglitazone-glimepiride (Duetact) combination.

PRIOR AUTHORIZATION

Patients with a contraindication to metformin and having a sulfonylurea fill for the previous 4 of 5 months may have pioglitazone. The 80% adherence rate must be maintained in order to maintain access to pioglitazone.

Patients with a contraindication to metformin and to sulfonylurea may have pioglitazone but will require a PA. No pioglitazone monotherapy.

This proposal allows access to pioglitazone prior to requiring basal insulin as the guidelines suggest. Use of pioglitazone is considered a less well-validated therapy than basal insulin.

Metformin must be taken at the maximally tolerated dose. Metformin use without titrating the dose slowly upwards is known to cause gastrointestinal side effects. Metformin 500mg twice daily is a starting dose. Many will require 1000mg twice daily.

The committee decided by consensus to approve the proposed step therapy guidelines for pioglitazone.

2. Pramlintide (Symlin, SymlinPen; both injectables)

Johnson informed the committee she could not put together a proposed step therapy guideline for Pramlintide because she did not find any useful evidence to support covering the drug.

Recommendation: Exclude New Users

The committee decided by consensus that everyone should start with metformin. Current user will be able to continue using the drug if they have hemoglobin A1C under 8% and they are a continuous user (4 out of 5 previous months on a continuing basis).

3. Exenatide (Byetta) Liraglutide (Victoza) (both injectables)

Recommendation: Proposed criteria for exenatide (Byetta) and liraglutide (Victoza):

1. Deny if any insulin claim in the past 30 days.
2. Continue no monotherapy access for exenatide or liraglutide.
3. PA all prescriptions
4. No therapeutic duplication. Do not allow concomitant exenatide and liraglutide use.

Initial PA, effective for 6 months:

- Require a current metformin fill for 120 of the past 150 days(4 out of 5 months) at the maximum or near-maximum dose (2000 mg daily), failure to reach goal A1C, AND
- Require, in patients who cannot tolerate metformin, the use of a sulfonylurea for 120 days and then the use of pioglitazone, unless contraindicated due to HF, edema, or fracture risk.
- Pioglitazone must be used for 120 days without achieving HbA1C goal before gaining access to exenatide or liraglutide.

Subsequent PA, effective for 1 year: (After patients have already been on Byetta or Victoza).

Allow access to exenatide or liraglutide if patient maintained metformin days supply of 150 of past 180 days unless contraindicated. If metformin is contraindicated, allow access to exenatide or liraglutide if patient maintained sulfonylurea and pioglitazone days supply of 150 of past 180 days. If either sulfonylurea or pioglitazone is contraindicated, require insulin use for a day's supply of 150 of past 180 days without achieving the goal prior to access to the GLP-2 analogs.

- ❖ Existing patients on either medication can continue if they are well controlled (HbA1C <8%) and compliant 4 out of the 5 past months on a rolling basis.

The committee decided by consensus to approve the recommendation for Exenatide (Byetta) Liraglutide (Victoza).

4. Sitagliptin (Januvia, Janumet), Saxagliptin (Onglyza, and Kombiglyze XR)

Proposed criteria for sitagliptin (Januvia) and saxagliptin (Onglyza) or any sitagliptin or saxagliptin-containing product:

1. Deny if any insulin claim in past 30 days.
2. Continue no monotherapy access for sitagliptin or saxagliptin.

Combination products require monotherapy prior to access (ie; Must fail metformin monotherapy as well as other combo therapies prior to getting this nonvalidated therapy.)

3. PA all prescriptions, criteria:
 - Require a current metformin fill for 120 of the past 150 days at the maximum or near-maximum dose, failure to reach goal A1C, AND then
 - Require the use of concomitant sulfonylurea (unless contraindicated) and then 120 of the past 150 days of pioglitazone in patients who have not reached their HbA1C goal with metformin monotherapy, unless pioglitazone is contraindicated due to HF, edema, or fracture risk.
 - Prior to access to Kombiglyze (saxagliptin + metformin), metformin + sulfonylurea + pioglitazone and without saxagliptin, must fail to achieve goal HbA1C.

No therapeutic duplication with sita- or saxa-gliptin. (Deny the drug if the other is filled in the previous 30 days.)

Metformin must be titrated slowly upward. Metformin 500mg twice daily is the initial dose. Patients should increase to at least 1000mg twice daily before determining failure. Metformin must have an adherence rate of 4 of the past 5 months prior to gaining access to sitagliptin or saxagliptin.

The committee decided by consensus to approve the recommendation for Sitagliptin (Januvia, Janumet), Saxagliptin (Onglyza, and Kombiglyze XR).

FIRST REVIEW MEDICATIONS

Drug Name

Tier Status

CYCLOSET TAB 0.8MG

Exclude

Cycloset, an ergot derivative, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Cycloset should not be used as a treatment of type 1 diabetes or diabetic ketoacidosis. There is limited efficacy data for the use of Cycloset in combination use with thiazolidinediones, and efficacy has not been confirmed in combination with insulin.

ELLA TAB 30MG

Exclude

ELLA can be used up to 5 days after unprotected intercourse or a known or suspected contraceptive failure. In comparison, PLAN B and PLAN B ONE-STEP should be used within 3 days per FDA

XGEVA INJ

Not Applicable

For the treatment of osteoporosis in postmenopausal women at high risk for fracture and for the prevention of skeletal-related events in patients with bone metastases from solid tumors

CARBAGLU TAB 200MG

T3/wPA Specialty

CARBAGLU (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated as: (1) adjunctive therapy for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) and (2) maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS).

BROMDAY Sol 0.09%

T3

BEYAZ TAB

Exclude

Beyaz (bee-YAZ) is a new version of Yaz with folate. Recommend using a generic OC plus a separate multivitamin or folic

PEDIADERM TA KIT

Exclude

| <u>Drug Name</u> | <u>Tier Status</u> |
|--|----------------------|
| PEDIADERM AF KIT COMPLETE | Exclude |
| ATELVIA TAB | T3 |
| EGRIFTA INJ 1MG | Exclude |
| KRYSTEXXA INJ | N/A Medical |
| TEFLARO INJ 600MG, Acute bacterial skin and skin structure infectioSSSI). Community acquired bacterial pneumonia (CABP) including MRSA. | 400mg Exclude |
| FIRST DUKES SUS MOUTHWSH Treatment of pain/inflammation associated with mucositis caused by radiation therapy or chemotherapy, aphthous and other oral ulcers, and mouth pain. | T3 |
| FIRST-MARYS SUS MOUTHWSH Treatment of pain/inflammation associated with mucositis caused by radiation therapy or chemotherapy, aphthous and other oral ulcers, and mouth pain. | T3 |
| LATUDA TAB 40, 80MG 40-80mg daily for the treatment of schizophrenia in adults. | Exclude |
| NEXICLON XR SUS 0.09/ML Dosage: 0.17mg daily at bedtime for hypertension. Max dose is 0.52mg/day. | Exclude |
| NEXICLON XR TAB 0.17MG Dosage: 0.17mg daily at bedtime for hypertension. Max dose is 0.52mg/day. | Exclude |
| NUEDEXTA CAP 20-10MG One 20/10mg tablet daily for 7 days then increase to one tablet every 12 hours for the treatment of pseudobulbar affect (PBA). PA criteria: 1. Dx of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS), and 2. Dx of clinically significant Pseudobulbar Affect (PBA) (a baseline score ≥ 13 on the Center for Neurologic Studies-Lability Sclase [CNS-LS]). | T3w/PA |
| ZOLPIMIST SPR 5MG 10mg (2 sprays) PO immediately before bedtime. | Exclude |
| MOXEZA SOL 0.5% One drop in each affected eye BID for 7 days for bacterial conjunctivitis. | T3 |

| <u>Drug Name</u> | <u>Tier Status</u> |
|--|-----------------------|
| OFIRMEV INJ 10MG/ML Intravenous acetaminophen (Ofirmev) approved for the treatment of pain/fever in adults and children over the age of 2 years. Adults, Adolescents 50kg or greater: 1000mg IV every six hours or 650mg IV every 4 hours as needed. | Exclude |
| SAFYRAL TAB Indicated for pregnancy prevention and to raise folate levels in women who want to use an oral contraceptive for contraception. One tablet PO daily following in order directed on package. | Exclude |
| XYNTHA INJ 3000UNIT Hemophilia | Tabled |
| AMTURNIDE150 TAB -5-12.5 Hypertension | T3 with ARB ST |
| AMTURNIDE300 TAB -10-12.5 Hypertension | T3 with ARB ST |
| AMTURNIDE300 TAB -10-25MG Hypertension | T3 with ARB ST |
| AMTURNIDE300 TAB -5-12.5 Hypertension | T3 with ARB ST |
| AMTURNIDE300 TAB -5-25MG Hypertension | T3 with ARB ST |
| FORTESTA GEL 10MG/ACT Hypogonadism PA Criteria: 1. Dx of testosterone deficiency in males OR hypogonadism or hypogonadotropic hypogonadism in males OR delayed puberty in males. | T3 w/PA |
| NATROBA SUS 0.9% Head Lice PA Criteria: 2. Requires 1 course of treatment of permethrins in the past 30 days. Allow no more than 2 fills per quarter. | T2 w/PA |
| PROHIST CD LIQ Antitussive/Decongestant/Antihistamine | Exclude |

| <u>Drug Name</u> | <u>Tier Status</u> |
|--|---------------------------|
| PROHIST CF LIQ Antitussive/Antihistamine | Exclude |
| PROIHIST LQ LIQ Antitussive/Low sedating antihistamine | Exclude |
| ALUVEA CRE 39% Dystrophic nail removal, mild kerosis, keratolytic | Exclude |
| ALUVEA CRE 43% Dystrophic nail removal, mild kerosis, keratolytic | Exclude |
| EDARBI 40MG ARB-hypertension | T3 ARB ST |
| EDARBI 80MG TAB ARB-Hypertension | T3 ARB ST |
| KAPVAY 0.1 mg tablet | Exclude |
| Axiron Soln Hypogonadism PA Criteria: Same as Androgel, Testim and Androderm | T2 w/PA |
| Benlysta inj For tx of active, autoantibody-positive, systemic lupus erythematosus (SLE) in combination with standard therapy. | N/A Medical |

ELECTION OF COMMITTEE CHAIR

Dr. Golden accepted nominations for the two-year term of Chairman of the DUEC. Neil nominated Hadley, Whitley seconded the nomination. After receiving no additional nominations, Dr. Golden closed the nominations. Hadley was declared elected by acclamation as Chair man of the DUEC.

Dr. Golden accepted nominations for the two-year term of Vice Chairman of the DUEC. Whitley nominated Neil. Dr. Simmons seconded the nomination. After receiving no additional nominations, Dr. Golden closed the nominations. Neil was declared elected by acclamation as Vice-Chair of the DUEC.

Meeting adjourned.

From February 2011 Insurance Board Meeting:

3.a. TZD's----The Board already voted to exclude coverage of Avandia, Avandamet and Avandaryl effective 7/1/2011 and we have that in place. However, there is still a determination to be made on Actos and what step therapy guidelines we should use.

3.b. Byetta and Victoza-----The Board was interested in Option 2 under your proposed recommendations.

Januvia, Janumet, Onglyza, and Kombiglyze XR-----The Board was interested in Option 2 under your proposed recommendations.

3.c. Symlin and Symlinpen----The Board was interested in developing step therapy criteria for these medications before they agree to exclude from coverage.

For all of these items, you will need to present final step therapy criteria at Monday's meeting so that those recommendations can be presented at the subsequent Board meeting. Jason doesn't want to go back through all of the clinical evidence but wants more defined step therapy criteria so that the Board will be able to understand how we are implementing the changes. Also, we need to be sure to include whether or not these changes will affect only new users of these medications, etc.

Antidiabetic Recommendations
Jill Johnson, Pharm.D., College of Pharmacy
4/3/11 Proposals:

Consensus Statement

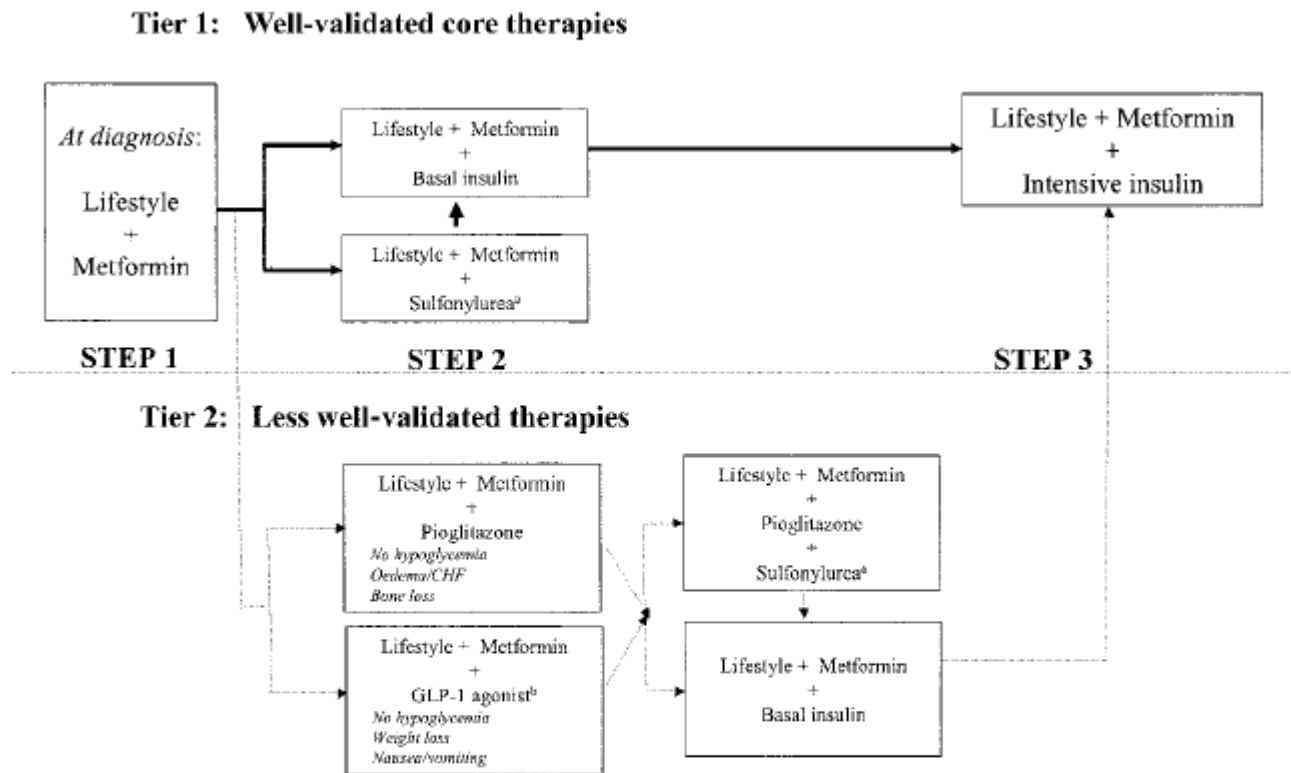


Figure 2—Algorithm for the metabolic management of type 2 diabetes; Reinforce lifestyle interventions at every visit and check A1C every 3 months until A1C is <7% and then at least every 6 months. The interventions should be changed if A1C is $\geq 7\%$. ^aSulfonylureas other than glyburide (glyburide) or chlorpropamide. ^bInsufficient clinical use to be confident regarding safety. See text box, entitled TITRATION OF METFORMIN. See Fig. 1 for initiation and adjustment of insulin. CHF, congestive heart failure.

EFFECTIVE: beginning 1/1/2012 for all new users of the considered drugs.

3a:

TZDs (rosiglitazone, pioglitazone), (Avandia, Avandaryl, Avandamet, Actos, ActoplusMet)

CURRENT

- No edits for EBD members

PROPOSED

- Restrict the access to rosiglitazone. Stop covering rosiglitazone (Avandia, Avandamet, Avandaryl) effective July 1, 2011.
- No pioglitazone (Actos) without metformin (at a near maximum daily dose-1000mg daily) or a contraindication to metformin.

4

4/3/11 Proposed step therapy guidelines for pioglitazone (Actos and Actos-containing products including pioglitazone-glimepiride, pioglitazone-metformin, and future combinations):

STEP THERAPY^a:

1. Patients taking metformin^b for the past 4 of 5 months and taking a sulfonylurea for the past 4 of 5 months may have pioglitazone. If the 80% adherence rate is not maintained, pioglitazone access will be denied at the point of sale.
2. Patients with a contraindication to metformin and having a sulfonylurea fill for the previous 4 of 5 months may have pioglitazone. The 80% adherence rate must be maintained in order to maintain access to pioglitazone.
3. Patients must adhere to at least 4 of the previous 5 months of metformin + sulfonylurea and fail to meet HbA1C goal prior to gaining access to pioglitazone-metformin (Actoplus Met) combination therapy.
4. Patients must adhere to at least 4 months of metformin monotherapy and an additional 4 months of metformin + sulfonylurea and fail to meet HbA1C goal prior to gaining access to pioglitazone-glimepiride (Duetact) combination.

PRIOR AUTHORIZATION

5. Patients with a contraindication to metformin and to sulfonylurea may have pioglitazone but will require a PA. No pioglitazone monotherapy.

^aThis proposal allows access to pioglitazone prior to requiring basal insulin as the guidelines suggest. Use of pioglitazone is considered a less well-validated therapy than basal insulin.

^bMetformin must be taken at the maximally tolerated dose. Metformin use without titrating the dose slowly upwards is known to cause gastrointestinal side effects. Metformin 500mg twice daily is a starting dose. Many will require 1000mg twice daily.

REFERENCES:

1. Nathan DM, Holman RR, Buse JB, Davidson MB, et al. Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy. *Diabetes Care*. 2009. 32:193–203. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\T2DM glycemc algorithm ADA 2009.pdf>
2. Drug Effectiveness Review Project. Oregon Health Sciences Center. Newer Diabetes Drugs. \\Copnt1\users\anyone shared\JohnsonJill\Diabetes_draft for final approval_report_original_Jan 2011.pdf

3b. Byetta and Victoza-----The Board was interested in Option 2 under your proposed recommendations.

Exenatide (Byetta) Liraglutide (Victoza)

CURRENT

- No monotherapy allowed
- 120 day lookback for 1 fill of metformin, sulfonylurea, or TZD.

PROPOSED

- Option 1.
 - Discontinue covering these drugs based on lack of outcomes evidence.
- Option 2.
 - Deny if any insulin claim in past 30d.
 - Continue no monotherapy access for exenatide or liraglutide.
 - PA all prescriptions, criteria:
 - require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND then
 - Require, in patients who cannot tolerate metformin, the use of a sulfonylurea or the use of pioglitazone, unless contraindicated due to HF, edema, or fracture risk.
- If renal function will not allow metformin (CrCl <30mL/min), then should not take exenatide either; For Victoza, use with caution with renal impairment, limited experience.

5

4/3/2011 Proposed criteria for exenatide (Byetta) and liraglutide (Victoza):

1. Deny if any insulin claim in the past 30 days.
2. Continue no monotherapy access for exenatide or liraglutide.
3. PA all prescriptions, criteria:

Initial PA, effective for 6 months:

- require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND
- Require, in patients who cannot tolerate metformin^{a, 1}, the use of a sulfonylurea² or the use of pioglitazone³, unless contraindicated due to HF, edema, or fracture risk.
- ^{b,c} Pioglitazone must be used for 120 days without achieving HbA1C goal before gaining access to exenatide or liraglutide.

Subsequent PA, effective for 1 year:

- Allow access to exenatide or liraglutide if patient maintained metformin days supply of 140 of past 180 days unless contraindicated. If metformin is contraindicated, allow access to exenatide or liraglutide if patient maintained sulfonylurea or pioglitazone days supply of 140 of past 180 days. If either sulfonylurea or pioglitazone is contraindicated, require insulin use for a days supply of 120 of past 180 days without achieving the goal prior to access to the GLP-2 analogs.

4. No therapeutic duplication. Do not allow concomitant exenatide and liraglutide use.

^aMetformin must be titrated slowly upward. Metformin 500mg twice daily is the initial dose.

^bThis proposal allows access to pioglitazone prior to requiring basal insulin as the guidelines suggest. Use of pioglitazone is considered a less well-validated therapy⁴ than basal insulin.

^c**Consider requiring basal insulin, a well-validated core therapy⁴, prior to using pioglitazone.**

References:

¹UKPDS 34. Lancet 1998; 352: 854–65. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 34.pdf>

²UKPDS 33. Lancet 1998; 352: 837–53. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 33.pdf>

³Lincoff AM, et al. **Pioglitazone and Risk of Cardiovascular Events in Patients With Type 2 Diabetes Mellitus** A Meta-analysis of Randomized Trials. *JAMA*. 2007;298(10):1180-1188. <C:\Documents and Settings\johnsonjill1\My Documents\Johnson\1Jill\My Dropbox\PDF's\Pioglitazone CV risk reduction-JAMA 07.pdf>

⁴Nathan DM, Holman RR, Buse JB, Davidson MB, et al. Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy. *Diabetes Care*. 2009. 32:193–203. <C:\Documents and Settings\johnsonjill1\My Documents\Johnson\1Jill\My Dropbox\PDF's\T2DM glycemc algorithm ADA 2009.pdf>

Januvia, Janumet, Onglyza, and Kombiglyze XR-----The Board was interested in Option 2 under your proposed recommendations.

Sitagliptin (Januvia, Janumet) Saxagliptin (Onglyza, Kombiglyze XR)

CURRENT

- No monotherapy allowed
- 120 day lookback for 1 fill of metformin

PROPOSED

- Option 1.
 - Discontinue covering these drugs based on lack of outcomes evidence.
- Option 2.
 - ***Deny if any insulin claim in past 30d.
 - Continue no monotherapy access for sitagliptin or saxagliptin.
 - PA all prescriptions, criteria:
 - Require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose failure to reach goal A1C, AND
 - Require the use of concomitant sulfonylurea &/or pioglitazone in patients who have not reached their HbA1C goal with metformin monotherapy, unless contraindicated due to HF, edema, or fracture risk.

***Sitagliptin has the FDA approval to be given with insulin for T2DM. There is no evidence regarding whether sitagliptin with or without insulin results in improved health outcomes. In the company-sponsored trial, sitagliptin + insulin + metformin was "well-tolerated". The A1C was 0.6% less in the sitagliptin group but the insulin arm was fixed.

6

4/3/2011 Proposed criteria for sitagliptin (Januvia) and saxagliptin (Onglyza) or any sitagliptin or saxagliptin-containing product:

1. Deny if any insulin claim in the past 30 days.
2. Continue no monotherapy access for sitagliptin or saxagliptin. Combination products require generic monotherapy prior to access.(i.e. Must fail metformin monotherapy as well as other generic combo therapies prior to getting this nonvalidated therapy.)
3. PA all prescriptions, criteria:
 - require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND then
 - Require the use of concomitant sulfonylurea, unless contraindicated, &/or pioglitazone in patients who have not reached HbA1C goal with metformin monotherapy, unless pioglitazone is contraindicated due to HF, edema, or fracture risk.
 - Prior to access to Kombiglyze XR (saxagliptin + metformin), metformin^b + sulfonylurea + pioglitazone and without saxagliptin must fail to achieve goal HbA1C.
4. No therapeutic duplication with sita- or saxa-gliptin. (Deny the drug if the other is filled in the previous 30 days.)

^aMetformin must be titrated slowly upward. Metformin 500mg twice daily is the initial dose. Patients should increase to at least 850 mg twice daily before determining failure.

^bMetformin must have an adherence rate of 4 of the past 5 months prior to gaining access to sitagliptin or saxagliptin.

References:

¹UKPDS 34. Lancet 1998; 352: 854–65. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 34.pdf>

²UKPDS 33. Lancet 1998; 352: 837–53. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 33.pdf>

³Lincoff AM, et al. **Pioglitazone and Risk of Cardiovascular Events in Patients With Type 2 Diabetes Mellitus A Meta-analysis of Randomized Trials.** JAMA. 2007;298(10):1180-1188. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\Pioglitazone CV risk reduction-JAMA 07.pdf>

3.c. Symlin and Symlinpen----The Board was interested in developing step therapy criteria for these medications before they agree to exclude from coverage.

Pramlintide (Symlin, Symlinpen)

CURRENT

- No edits

PROPOSED

- Exclude

4/3/11 Proposed Step Therapy:

1. None^a.

^aNo proposed step therapy due to no evidence of reduction in any diabetes related events, an increased risk of severe hypoglycemia when given with insulin, increased risk of nausea (30% of patients), slowed gastric emptying (in patients already at risk for diabetic gastroparesis), and only a 0.7% reduction in HbA1C at best, again without evidence of risk reduction.

DUEC New Drugs Oct-Dec 2010

| Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | | AWP per unit | Estimated AWP/month | Indications | Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|-------------------------|---|--|--|-------------------|-------------------------------------|---|--|---|-----------|----------------|
| CYCLOSET TAB 0.8MG | BROMOCRIPTINE MESYLATE TAB 0.8 MG (BASE EQUIVALENT) | metformin \$42-\$108 per 30 days, sulfonylureas \$10-\$93, per 30 days | Actos 15-45mg \$173.40--\$287.40 per month, januvia \$226.50 per month | 1.8 per 0.8mg tab | 2- 6 ta/day (\$108-\$324 per month) | Cycloset, an ergot derivative, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Cycloset should not be used as a treatment of type 1 diabetes or diabetic ketoacidosis. There is limited efficacy data for the use of Cycloset in combination use with thiazolidinediones, and efficacy has not been confirmed in combination with insulin. | Cycloset is a novel therapy directly targeting the body's dopamine activity to improve glycemic control. It provides physicians with another treatment option for their patients with type 2 diabetes. • Unlike many other currently available drugs that stimulate insulin release, Cycloset improves glycemic control without increasing circulating insulin levels. | Exclude at this time. Has not been compared to metformin. No outcomes except HbA1C. | | |
| KOMBIGLYZE TAB 2.5-1000 | SAXAGLIPTIN-METFORMIN HCL TAB SR 24HR 2.5-1000 MG | Janumet 50-500mg and 50-1000mg 3.77 | \$226.30 per month | 3.67 | \$110.10 per month | For the treatment of type 2 diabetes mellitus in combination with diet and exercise when treatment with both saxagliptin and metformin is appropriate | Tier 3 with step (like Janumet) | T3 with lookback 180d for metformin monotherapy. | | |
| KOMBIGLYZE TAB 5-1000MG | SAXAGLIPTIN-METFORMIN HCL TAB SR 24HR 5-1000 MG | Janumet 50-500mg and 50-1000mg 3.77 | | 7.34 | \$220.20 per month | | Tier 3 with step (like Janumet) | " | | |
| KOMBIGLYZE TAB 5-500MG | SAXAGLIPTIN-METFORMIN HCL TAB SR 24HR 5-500 MG | Janumet 50-500mg and 50-1000mg 3.77 | | 7.34 | \$220.20 per month | | Tier 3 with step (like Janumet) | " | | |
| ELLA TAB 30MG | ULIPRISTAL ACETATE TAB 30 MG | Plan B, Plan B one step, Next Choice | Plan b \$15.88 per tab= \$31.76 per dose, plan B one step \$40.62, Next Choice average generic \$14.62 | 42.90 | | ELLA can be used up to 5 days after unprotected intercourse or a known or suspected contraceptive failure. In comparison, PLAN B and PLAN B ONE-STEP should be used within 3 days per FDA | A disadvantage to ELLA is its Rx-only availability. PLAN B and PLAN B ONE-STEP are available over-the-counter (OTC) for patients > 17 years of age; both are Rx for those < 17 years of age. ► PLAN B is available generically as NEXT . exclude, same as Plan B | Exclude, OTC alternatives | | |
| XGEVA INJ | DENOSUMAB INJ 120 MG/1.7ML | Same drug as Prolia, different indications | Prolia 60mg \$990/unit | 1164.71 | \$1165 (120mg every 4 weeks) | For the treatment of osteoporosis in postmenopausal women at high risk for fracture and For the prevention of skeletal-related events in patients with bone metastases from solid tumors | exclude (same as Prolia) | Medical N/A | | |
| CARBAGLU TAB 200MG | CARGLUMIC ACID TAB 200 MG | There are 2 currently marketed products known as "nitrogen scavengers," Medicis Pharmaceutical Corp's AMMONUL (sodium phenylacetate/sodium benzoate) and BUPHENYL (sodium phenylbutyrate) approved | Ammonul \$2,866.80 per 50 mL single-use vial Child: \$5,733.60 Adult: \$11,467.20 for 30 day supply. Buphenyl \$7.72 per tablet; \$3,857.38 per 250 gram can Child: \$3,857.38 - | 159.60 | \$5586 per day | CARBAGLU (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated as: (1) adjunctive therapy for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) and (2) maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). | CARBAGLU is the only product FDA-approved as a specific treatment of hyperammonemia due to NAGS deficiency. Other available treatments are unspecific for this indication. | PA T3. Specialty | | |
| BROMDAY SOL 0.09% | BROMFENAC SODIUM OPHTH SOLN 0.09% (BASE EQUIV) (ONCE-DAILY) | Xibrom | | 91.18 | 1.700ML | | | | | |

| Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|---------------------------|--|--|--------------|---|---|---|--------------------|--------------------|--------------------|
| GILENYA CAP 0.5MG | FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV) | Avonex, Betaseron, COPAXONE, EXTAVIA, NOVANTRONE, REBIF, TYSABRI (vs. \$2,800 - \$3,200 month for injectable therapies) | 158.08 | \$4426 per 28 day supply | GILENYA (fingolimod) is the first oral therapy approved for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. GILENYA belongs to a new class of drugs called sphingosine-1-phosphate receptor (S1P) modulator | Current treatment guidelines recommend that initiation of interferon beta or glatiramer acetate should be considered when a diagnosis of relapsing disease is made. Natalizumab is generally reserved for patients who had an inadequate response or were unable to tolerate other MS therapies. Mitoxantrone is reserved for relapsing patients with worsening disease or patients with secondary progressive disease, whether or not relapses are occurring. first in class drug that prevents white cell release from lymph nodes, which attach the myelin sheath... risk of toxicity for the heart, lung & eye along with increase risk of infection. | T3 w PA. Specialty | T3 w PA. Specialty | T3 w PA. Specialty |
| GLASSIA INJ | PROTEINASE INHIBITOR (HUMAN) INJ 1000 MG/50ML | ARALAST - PROLASTIN -ZEMAIRA - | 11.04 | Single use vial 1 gram Alpha1-PI in 50 mL Solution 60 mg/kg body weight | | | Exclude. Specialty | | |
| BEYAZ TAB | DROSPIRENONE-ETHINYL ESTRAD-LEVOMEFOLATE TAB 3-0.02-0.451 MG | compared to about \$50 for the generic without folate (Gianvi) plus \$2 for a folate supplement | 3.04286 | 85.12 | | Beyaz (bee-YAZ) is a new version of Yaz with folate. recommend using a generic OC plus a separate multivitamin or folic | Exclude | | |
| PEDIADERM TA KIT | *TRIAMCINOLONE CREAM 0.1% & EMOLLIENT CREAM KIT** | | 1.45043 | | | exclude kits | Exclude | | |
| PEDIADERM AF KIT COMPLETE | *NYSTATIN CREAM 100000 UNIT/GM & DIAPER RASH CREAM KIT** | | 1.15833 | | | exclude kits | Exclude | | |

| Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|-----------------------|---|---|--------------|--|--|---|--|-----------------------------------|----------------------------------|
| PRADAXA CAP 75, 150MG | DABIGATRAN ETEXILATE MESYLATE CAP | warfarin \$23/month | 4.05 | \$8.10 per day and/or \$243 per 30 day supply. | PRADAXA is the first oral direct thrombin inhibitor (a type of anticoagulant). It is FDA-approved to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF). PRADAXA will be competing with warfarin (COUMADIN, JANTOVEN), the existing "gold standard" oral anticoagulant that has been on the market for over 50 years. PRADAXA was designed to overcome the disadvantages of warfarin, specifically regarding onset of action and dissipation, predictability of anticoagulant effect, probability of food-drug interactions, and need for monitoring. PRADAXA is also being studied for other conditions such as venous thromboembolism (which will open the market for it to compete against heparin and low molecular weight heparins (LMWH)). | * Significant decrease risk of bleeding complications as compared to warfarin. Cost effectiveness study in the Annals of Internal Medicine supports this. * More predictable anticoagulant action thus less frequent coagulation monitoring & dosage adjustments * More rapid onset and offset of action. * Low risk of drug interactions To mitigate the risks of bleeding associated with the use of PRADAXA, the drug will be subject to a risk evaluation and mitigation strategy (REMS). A Medication Guide will be required to be dispensed along with each prescription informing patients of the serious risks associated with PRADAXA, particularly the increased risk of bleeding and how such symptoms should be recognized. : Cover with a daily dose limit of 2 per day. | T3 | T3 PA: 1. Dx of AF. QL of 62/32d. | T2 PA: 1. Dx of AF. QL of 62/32. |
| AELVIA TAB | RISEDRONATE SODIUM TAB DELAYED RELEASE 35 MG | Actonel 35mg | 30.45 | \$121.76 | | | | T3 | |
| EGRIFTA INJ 1MG | TESAMORELIN ACETATE FOR INJ 1 MG (BASE EQUIV) | | 39.29 | | | | Exclude. Whether Egrifta decreases the risk of cardiovascular disease or improves compliance with antiretroviral drugs has not been studied. | | |
| KRYSTEXXA INJ 8MG/ML | PEGLOTICASE INJ 8 MG/ML (FOR IV INFUSION) | | 1,380.00 | | | | N/A Medical. | | |

DUEC New Drugs Jan-March 2011

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|----------------------------|-----------------------------|---|---|---|-----------------------|-------------|---|--|---|----------------|
| 0250 0030 1021 ** | TEFLARO INJ 600MG, 400mg | CEFTAROLINE FOSAMIL FOR IV SOLN 600 MG | Cubicin/Tyagacil/Vancomycin/Vibativ | NA | 49.2 | NA | Acute bacterial skin and skin structure infectio(SSSI). Community acquired bacterial pneumonia (CABP) including MRSA. | exclude IV | Exclude. This should be an inpatient drug or one supplied by a home infusion company and would be covered by medical. | |
| 8810 9903 4918 20 | FIRST DUKES SUS MOUTHWSH | *DIPHENHYDRAMINE- HYDROCORTISONE- NYSTATIN SUSP*** | available as separate components to compound | \$25-30 | 0.173 | \$41.00 | Treatment of pain/inflammation associated with mucositis caused by radiation therapy or chemotherapy, aphthous and other oral ulcers, and mouth pain. | Each compounding kit is made for one patient and include pre-weighed powders and pre-measured suspension for the pharmacist to reconstitute. alternative to compound RX | T3. Pharmacist-compounded products are reimbursed at the T3 level. A T3 copay would cover this completely as long as \$41 is for a 31 days supply. | |
| 8810 9904 6018 20 | FIRST-MARYS SUS MOUTHWSH | *DIPHENHYDRAMINE- HYDROCORTISONE- NYSTATIN- TETRACYCLINE SUSP** | available as separate components to compound | \$25-30 | 0.18354 | \$43.50 | Treatment of pain/inflammation associated with mucositis caused by radiation therapy or chemotherapy, aphthous and other oral ulcers, and mouth pain. | Each compounding kit is made for one patient and include pre-weighed powders and pre-measured suspension for the pharmacist to reconstitute. alternative to compound RX | T3. Pharmacist-compounded products are reimbursed at the T3 level. A T3 copay would cover this completely as long as \$41 is for a 31 days supply. | |
| 5940 0023 1003 ** | LATUDA TAB 40 80MG | LURASIDONE HCL TAB 80 MG | Abilify/Geodon/Invega/risperidone/Saphris/Seroquel XR/Zyprexa | #330-610 | 16.8 | \$504 | 40-80mg daily for the treatment of schizophrenia in adults. | May offer an early onset of action (3 days). Early data indicates lower weight gain compared to olanzapine. Lacks long-term safety and efficacy data. All the pivotal phase III clinical trials were limited to 6 weeks duration.add to tier 2 | Exclude. Latuda has only 4 six-week placebo controlled trials. There is no evidence for superiority because it has not been compared to any active controlled use where the trial was powered to find any clinical difference. Re-search the literature in 6 months for comparative data. | |
| 4910 2030 0020 60 | CUVPOSA SOL 1MG/5ML | GLYCOPYRROLATE ORAL SOLN 1 MG/5ML | GLYCOPYRROLATE tablet 1 and 2mg | \$1.05/1MG TAB | 0.95 or \$4.75/5ml | | For the reduction of severe chronic drooling in patients with neurologic conditions associated with drooling (e.g., cerebral palsy). Dosage: Children/adolescents max dose: 0.1mg/kg/dose TID | Only oral solution available but generic 1mg tab available | T3 | |
| 3620 1010 1011 20 | NEXICLON XR SUS 0.09/ML | CLONIDINE HCL EXTENDED RELEASE SUSP 0.09 MG/ML (BASE EQUIV) | Jenloga/Kapvay/clonidine/Catapres TTS | 30 mday supply:: Clonidine IR- \$33;Kapvay XR-\$151; Catapres TTS-\$95 | 2.44068 | \$366/mo | Dosage: 0.17mg daily at bedtime for hypertension. Max dose is 0.52mg/day. | Extended release oral suspension form; exclude-generic available | Exclude; IR tablets can be crushed. Extemporaneously prepared 0.1mg/mL oral suspension may be made from tablets. Directions in LexiComp. This clonidine is for HTN. | |
| 3620 1010 1075 10 | NEXICLON XR TAB 0.17MG | CLONIDINE HCL TAB SR 24HR 0.17 MG (BASE EQUIVALENT) | Jenloga/Kapvay/clonidine/Catapres | 30 mday supply:: Clonidine IR- \$33;Kapvay XR-\$151; Catapres TTS-\$95 | 4.8 | \$288/mo | Dosage: 0.17mg daily at bedtime for hypertension. Max dose is 0.52mg/day. | exclude-generic available | Exclude. This clonidine is for HTN. | |

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|----------------------------|------------------------------|--|---|---|---------------------|--|--|---|--|----------------|
| 6260 9902 3001 20 | NUEDEXTA CAP 20-10MG | DEXTROMETHORPHAN HBR-QUINIDINE SULFATE CAP 20-10 MG | NA | 9.78 | \$586.80 | One 20/10mg tablet daily for 7 days then increase to one tablet every 12 hours for the treatment of pseudobulbar affect(PBA) | This combo first FDA approved treatment for PBA occurs secondary to various unrelated neurological conditions and is characterized by uncontrollable episodes of laughing and/or crying. cover with QL of 2 per day | T3 with PA. 1. Dx of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS), and 2. Dx of clinically significant Pseudobulbar Affect (PBA) (a baseline score ≥13 on the Center for Neurologic Studies-Lability Scale [CNS-LS]). (not effective for heroin detox). The quinidine increases dextromethorphan's bioavailability by 20-fold. The dextromethorphan is what treats the disease. | | |
| 6020 4080 1020 20 | ZOLPIMIST SPR 5MG | ZOLPIDEM TARTRATE ORAL SPRAY 5 MG/ACT | Ambien,Ambien CR, Edluar. | 30 day supply: \$204-385 | 9.35065 | \$72.00 | 10mg (2 sprays) PO immediately before bedtime. | Oral spray dosage form.exclude-generic available | Exclude | |
| 8610 1038 1020 25 | MOXEZA SOL 0.5% | MOXIFLOXACIN HCL OPTH SOLN 0.5% (BASE EQ) (2 TIMES DAILY) | Vigamox | \$30.58/ML \$92.00/7 DAY | 30.58 | \$92.00/7 DAYS | One drop in each affected eye BID for 7 days for bacterial conjunctivitis. | Moxeza needs only to be administered twice daily vs Vigamox TID.add to tier 3 (same as Vigamox) | Which tier is Vigamox? (place at same tier; negotiate for T2 if rebates available) Moxeza provided total peak and superior exposure vs Vigamox. Whether this translates into cost-effective medication | |
| 6420 0010 0020 70 | OFIRMEV INJ 10MG/ML | ACETAMINOPHEN IV SOLN 10 MG/ML | NA | 0.129 | | | Intravenous acetaminophen (Ofirmev) approved for the treatment of pain/fever in adults and children over the age of 2 years.Adults,Adolescents 50kg or greater: 1000mg IV every six hours or 650mg IV every 4 hours as needed. | Exclude-generic available and IV dosage form | Exclude. IV; not outpatient drug. | |
| 2599 0003 2003 30 | SAFYRAL TAB | DROSPIRENONE-ETHINYL ESTRADILEVOMEFOLATE TAB 3-0.03-0.451 MG | Beyaz \$85.12 per month | 3.04286 | \$85.12 | Indicated for pregnancy prevention and to raise folate levels in women who want to use an oral contraceptive for contraception.One tablet PO daily following in order directed on package. | recommend using a generic OC plus a separate multivitamin or folic acid supplement | Exclude; consider reference pricing with all OC's. | | |
| 8510 0010 2664 70 | XYNTHA INJ 3000UNIT | ANTIHEMOPHILIC FACTOR RECOMBINANT PAF FOR INJ KIT 3000 UNIT | Kogenate, Humate, Alphante | \$0.50-\$2.17/unit 3000units/\$3,600-\$%,040 | 1.66 | 3000 units = \$4,980 | Hemophilia | Antihemophilic factors covered with PA at Ascend | Specialty. T3 PA. | |
| 3699 6803 2003 20 | AMTURNIDE150 TAB -5-12.5 | ALISKIREN-AMLODIPINE-HYDROCHLOROTHIAZIDE TAB 150-5-12.5 MG | Tekturma HCT and amlodipine | Tekturma HCT 3.21 | 2.976 | \$89.28 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 3699 6803 2003 40 | AMTURNIDE300 TAB -10-12.5 | ALISKIREN-AMLODIPINE-HYDROCHLOROTHIAZIDE TAB 300-10-12.5 MG | Tekturma HCT and amlodipine | Tekturma HCT 4.25 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|----------------------------|--|---|---|--|---------------------|--------------------|---|---|---|----------------|
| 3699 6803 2003 45 | AMTURNIDE300 TAB -5-12.5MG | ALISKIREN- AMLODIPINE- HYDROCHLOROTH AZIDE TAB 300-10- 25 MG | Tektuma HCT and amlodipine | Tektuma HCT 4.34 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 3699 6803 2003 30 | AMTURNIDE300 TAB -5-12.5 | ALISKIREN- AMLODIPINE- HYDROCHLOROTH AZIDE TAB 300-5- 12.5 MG | Tektuma HCT and amlodipine | Tektuma HCT 4.06 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 3699 6803 2003 35 | AMTURNIDE300 TAB -5-25MG | ALISKIREN- AMLODIPINE- HYDROCHLOROTH AZIDE TAB 300-5-25 MG | Tektuma HCT and amlodipine | Tektuma HCT 4.34 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 6510 0025 1007 ** | ABSTRAL SUB 100MCG, 200, 400, 600, 800 | FENTANYL CITRATE SL TAB 100 MCG (BASE EQUIV) | Fentora, Onsolis, Fentanyl, Actiq | 22.58-59.76 100 to 800mcg for Fentora, 23.33-67.08 Onsolis 45-150 for actiq, 18.80 -\$55.43 for generic Actiq | 16.8- 48 | | Abstral is indicated for the management of breakthrough pain in patients with cancer, ages 18 years and older, who already use opioid pain medication around the clock and who need and are able to safely use high doses of an additional opioid medicine. | Abstral is available only through a Risk Evaluation and Mitigation Strategy (REMS) program, which is intended to minimize the risk of misuse, abuse, addiction and overdose. Under this program, pharmacies, distributors, and health care professionals who prescribe to outpatients are required to enroll in the program to prescribe, dispense and distribute this product. | T3 PA. QL of 4 tabs/1 day or 120/30d. PA criteria: 1. Dx of cancer AND on who are taking at least 60 mg of oral morphine/daily, or at least 25 mcg transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg oral hydromorphone daily, at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. ABSTRAL is indicated only for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. | |
| 2310 0030 0040 70 | FORTESTA GEL 10MG/ACT | TESTOSTERONE TD GEL 10MG/ACT (2%) | Androgel , Testim, Androderm | Androgel \$333.00, Androderm \$325 | 5.01483 | \$300 per 60gm | Hypogonadism | Androgel, Testim and Androderm tier 2 with PA | T3, PA: 1. Dx of testosterone deficiency in males OR hypogonadism or hypogonadotropic hypogonadism in males OR delayed puberty in males. (We should select one testosterone topical and negotiate for rebates.) | |
| 9090 0048 0018 20 | NATROBA SUS 0.9% | SPINOSAD SUSP 0.9% | Lindane lotion, shampoo-\$15-\$91 Elimite \$79.80 | Pronto OTC \$12 | 1.99 | \$238.80/4 oz | Head Lice | exclude, less expensive options available | T2 w/ ST: Require 2 fills of permethrins in the past 30 days. (Permethrins is 1st line tx by the American Academy of Pediatrics). | |
| 4399 5803 75** | PROHIST CD LIQ | PHENYLEPH- TRIPROLDINE- CHLORPHEDIANOL 10-2.5-25MG/5ML | Brotapp DM, C- Phen | \$0.04/ml \$4.80/120ml | 0.18867 | \$22.64/12 0ml | Antitussive/Decongestant/A ntihistamine | Multiple generics available - exclude | Exclude. Generic alternatives. Not in Drug Facts and Comparisons. Accessed 3/28/11. | |
| 4399 5702 0709 ** | PROHIST CF LIQ | CHLORPHEDIANOL- TRIPROLDINE 25- 2.5MG/5ML | Promethazine DM | \$0.04/ml \$4.80/120ml | 0.18867 | \$22.64/12 0ml | Antitussive/Antihistamine | Exclude- generic available | Exclude. Generic alternatives. Not in Drug Facts and Comparisons. Accessed 3/28/11. | |
| 4399 3002 8309 ** | PROIHIST LQ LIQ | TRIPROLDINE- PHENYLEPHRINE LIQ 2.5-10MG/5ML | Triproline/PSE syrup | \$0.64/ml \$7.68/120ml | 0.18867 | \$22.64/12 0ml | Antitussive/Low sedating antihistamine | Exclude - generic available | Exclude. Generic alternatives. Not in Drug Facts and Comparisons. Accessed 3/28/11. | |
| 906 600 800 007 | ALUVEA CRE 39% | UREA 39% | Urea 50% cream | \$1.12/gm \$159.00/142gm | 1.5806 | \$224.36/1 42gm | Dystrophic nail removal , mild kerosis, keratolytic | exclude-generic available | exclude. Generics available. | |

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|--------------------------|----------------------|---------------------------|---|------------------------------------|--------------------------------|--|--|---|---|----------------|
| 906 600 800 007 | ALUVEA CRE 43% | UREA 43% | Urea 50% cream | \$1.12/gm \$159.00/142gm | 1.5806 | \$224.36/142gm | Dystrophic nail removal , mild kerosis , keratolytic | exclude-generic available | exclude. Generics available. | |
| 361 500 102 003 | EDARBI 40MG | AZILSARTAN MEDOXOMIL 40MG | Cozaar,Atacand,Diovan,Avapro, Losartan,Micardis,Teveten,Benicar | \$90-114/month | 2.94 | \$88.20 | ARB-hypertension | Tier 3 with step therapy | T3 ARB ST | |
| 361 500 102 003 | EDARBI 80MG TAB | AZILSARTAN MEDOXOMIL 80MG | Cozaar,Atacand,Diovan,Avapro, Losartan,Micardis,Teveten,Benicar | \$90-114/month | 2.94 | \$88.20 | ARB-Hypertension | Tier 3 with step therapy | T3 ARB ST | |
| | Kapvay 0.1 mg tablet | clonidine XR | clonidine 0.1mg tab, MAC=\$0.04 | \$2 | AWP per tab = \$2.52 | \$151 | | | This clonidine is for ADHD. Exclude. This is administered BID like the IR except it is not interchangeable. PI states longterm use (>5w) has not been studied. In 1 trial vs placebo, it was superior to placebo @5w. | |
| | Axiron Soln | Testosterpme TD Soln | Androgel , Testim, Androderm | Androgel \$333.00, Androderm \$325 | \$3.71 | \$334.32/90ml | Hypogonadism | Androgel, Testim and Androderm tier 2 with PA | | |
| | Benlysta inj | Belimumab IV soln | | | \$531/120mg \$1772.71/400mg | For tx of active, autoantibody-positive, systemic lupus erythematosus (SLE) in combination with standard therapy | 10m/kg/dose IV every 2 weeks for the first 3 doses then every 2 weeks thereafter. Only healthcare providers prepared to manage anaphylaxis should administer Benlysta. | No peer-reviewed trials in pubmed. From PI, did not work in Blacks. Mortality was higher with the drug than with placebo. Only worked in auto-antibody positive patients. | | |

From February 2011 Insurance Board Meeting:

3.a. TZD's----The Board already voted to exclude coverage of Avandia, Avandamet and Avandaryl effective 7/1/2011 and we have that in place. However, there is still a determination to be made on Actos and what step therapy guidelines we should use.

3.b. Byetta and Victoza-----The Board was interested in Option 2 under your proposed recommendations.

Januvia, Janumet, Onglyza, and Kombiglyze XR-----The Board was interested in Option 2 under your proposed recommendations.

3.c. Symlin and Symlinpen----The Board was interested in developing step therapy criteria for these medications before they agree to exclude from coverage.

For all of these items, you will need to present final step therapy criteria at Monday's meeting so that those recommendations can be presented at the subsequent Board meeting. Jason doesn't want to go back through all of the clinical evidence but wants more defined step therapy criteria so that the Board will be able to understand how we are implementing the changes. Also, we need to be sure to include whether or not these changes will affect only new users of these medications, etc.

Antidiabetic Recommendations
Jill Johnson, Pharm.D., College of Pharmacy
4/3/11 Proposals:

Consensus Statement

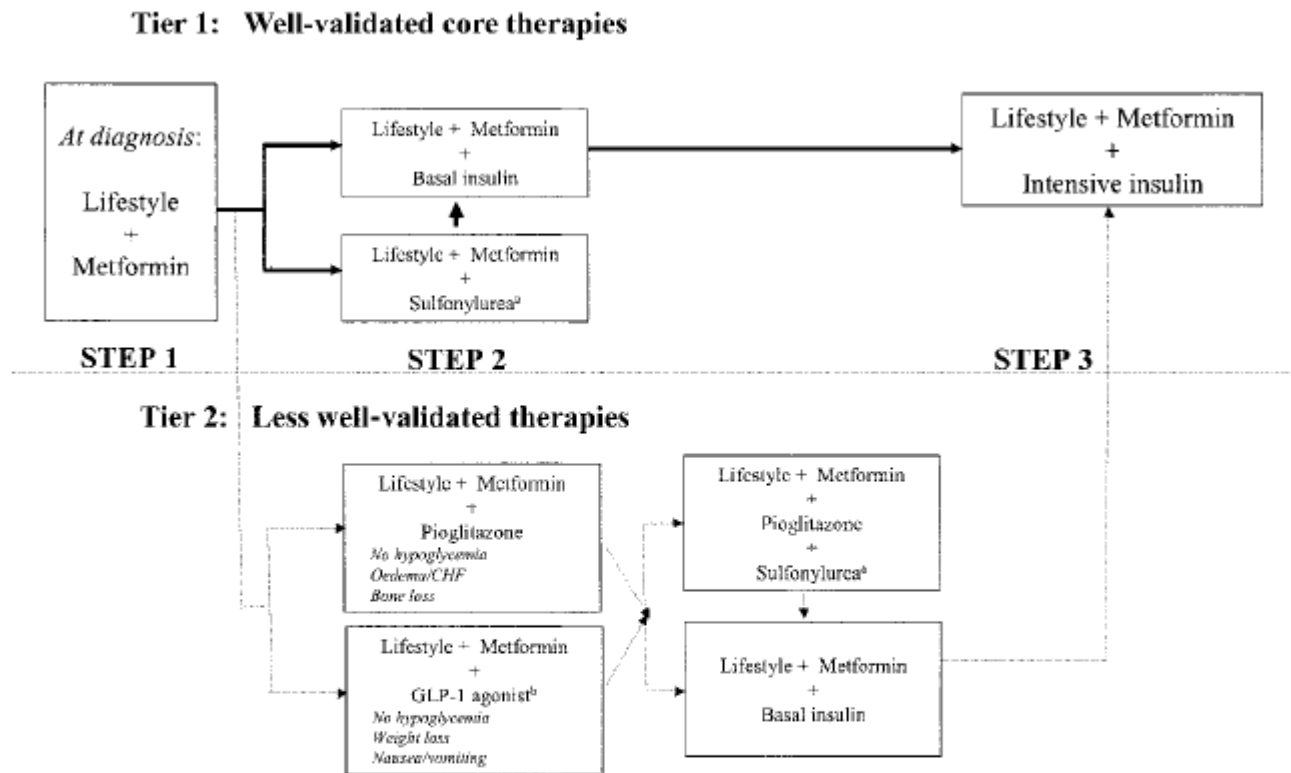


Figure 2—Algorithm for the metabolic management of type 2 diabetes; Reinforce lifestyle interventions at every visit and check A1C every 3 months until A1C is <7% and then at least every 6 months. The interventions should be changed if A1C is $\geq 7\%$. ^aSulfonylureas other than glyburide (glyburide) or chlorpropamide. ^bInsufficient clinical use to be confident regarding safety. See text box, entitled TITRATION OF METFORMIN. See Fig. 1 for initiation and adjustment of insulin. CHF, congestive heart failure.

EFFECTIVE: beginning 1/1/2012 for all new users of the considered drugs.

3a:

TZDs (rosiglitazone, pioglitazone), (Avandia, Avandaryl, Avandamet, Actos, ActoplusMet)

CURRENT

- No edits for EBD members

PROPOSED

- Restrict the access to rosiglitazone. Stop covering rosiglitazone (Avandia, Avandamet, Avandaryl) effective July 1, 2011.
- No pioglitazone (Actos) without metformin (at a near maximum daily dose-1000mg daily) or a contraindication to metformin.

4

4/3/11 Proposed step therapy guidelines for pioglitazone (Actos and Actos-containing products including pioglitazone-glimepiride, pioglitazone-metformin, and future combinations):

STEP THERAPY^a:

1. Patients taking metformin^b for the past 4 of 5 months and taking a sulfonylurea for the past 4 of 5 months may have pioglitazone. If the 80% adherence rate is not maintained, pioglitazone access will be denied at the point of sale.
2. Patients with a contraindication to metformin and having a sulfonylurea fill for the previous 4 of 5 months may have pioglitazone. The 80% adherence rate must be maintained in order to maintain access to pioglitazone.
3. Patients must adhere to at least 4 of the previous 5 months of metformin + sulfonylurea and fail to meet HbA1C goal prior to gaining access to pioglitazone-metformin (Actoplus Met) combination therapy.
4. Patients must adhere to at least 4 months of metformin monotherapy and an additional 4 months of metformin + sulfonylurea and fail to meet HbA1C goal prior to gaining access to pioglitazone-glimepiride (Duetact) combination.

PRIOR AUTHORIZATION

5. Patients with a contraindication to metformin and to sulfonylurea may have pioglitazone but will require a PA. No pioglitazone monotherapy.

^aThis proposal allows access to pioglitazone prior to requiring basal insulin as the guidelines suggest. Use of pioglitazone is considered a less well-validated therapy than basal insulin.

^bMetformin must be taken at the maximally tolerated dose. Metformin use without titrating the dose slowly upwards is known to cause gastrointestinal side effects. Metformin 500mg twice daily is a starting dose. Many will require 1000mg twice daily.

REFERENCES:

1. Nathan DM, Holman RR, Buse JB, Davidson MB, et al. Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy. *Diabetes Care*. 2009. 32:193–203. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\T2DM glycemc algorithm ADA 2009.pdf>
2. Drug Effectiveness Review Project. Oregon Health Sciences Center. Newer Diabetes Drugs. \\Copnt1\users\anyone shared\JohnsonJill\Diabetes_draft for final approval_report_original_Jan 2011.pdf

3b. Byetta and Victoza-----The Board was interested in Option 2 under your proposed recommendations.

Exenatide (Byetta) Liraglutide (Victoza)

CURRENT

- No monotherapy allowed
- 120 day lookback for 1 fill of metformin, sulfonylurea, or TZD.

PROPOSED

- Option 1.
 - Discontinue covering these drugs based on lack of outcomes evidence.
- Option 2.
 - Deny if any insulin claim in past 30d.
 - Continue no monotherapy access for exenatide or liraglutide.
 - PA all prescriptions, criteria:
 - require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND then
 - Require, in patients who cannot tolerate metformin, the use of a sulfonylurea or the use of pioglitazone, unless contraindicated due to HF, edema, or fracture risk.
- If renal function will not allow metformin (CrCl <30mL/min), then should not take exenatide either; For Victoza, use with caution with renal impairment, limited experience.

5

4/3/2011 Proposed criteria for exenatide (Byetta) and liraglutide (Victoza):

1. Deny if any insulin claim in the past 30 days.
2. Continue no monotherapy access for exenatide or liraglutide.
3. PA all prescriptions, criteria:

Initial PA, effective for 6 months:

- require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND
- Require, in patients who cannot tolerate metformin^{a, 1}, the use of a sulfonylurea² or the use of pioglitazone³, unless contraindicated due to HF, edema, or fracture risk.
- ^{b,c} Pioglitazone must be used for 120 days without achieving HbA1C goal before gaining access to exenatide or liraglutide.

Subsequent PA, effective for 1 year:

- Allow access to exenatide or liraglutide if patient maintained metformin days supply of 140 of past 180 days unless contraindicated. If metformin is contraindicated, allow access to exenatide or liraglutide if patient maintained sulfonylurea or pioglitazone days supply of 140 of past 180 days. If either sulfonylurea or pioglitazone is contraindicated, require insulin use for a days supply of 120 of past 180 days without achieving the goal prior to access to the GLP-2 analogs.

4. No therapeutic duplication. Do not allow concomitant exenatide and liraglutide use.

^aMetformin must be titrated slowly upward. Metformin 500mg twice daily is the initial dose.

^bThis proposal allows access to pioglitazone prior to requiring basal insulin as the guidelines suggest. Use of pioglitazone is considered a less well-validated therapy⁴ than basal insulin.

^c**Consider requiring basal insulin, a well-validated core therapy⁴, prior to using pioglitazone.**

References:

¹UKPDS 34. Lancet 1998; 352: 854–65. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 34.pdf>

²UKPDS 33. Lancet 1998; 352: 837–53. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 33.pdf>

³Lincoff AM, et al. **Pioglitazone and Risk of Cardiovascular Events in Patients With Type 2 Diabetes Mellitus** A Meta-analysis of Randomized Trials. *JAMA*. 2007;298(10):1180-1188. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\Pioglitazone CV risk reduction-JAMA 07.pdf>

⁴Nathan DM, Holman RR, Buse JB, Davidson MB, et al. Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy. *Diabetes Care*. 2009. 32:193–203. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\T2DM glycemc algorithm ADA 2009.pdf>

Januvia, Janumet, Onglyza, and Kombiglyze XR-----The Board was interested in Option 2 under your proposed recommendations.

Sitagliptin (Januvia, Janumet) Saxagliptin (Onglyza, Kombiglyze XR)

CURRENT

- No monotherapy allowed
- 120 day lookback for 1 fill of metformin

PROPOSED

- Option 1.
 - Discontinue covering these drugs based on lack of outcomes evidence.
- Option 2.
 - ***Deny if any insulin claim in past 30d.
 - Continue no monotherapy access for sitagliptin or saxagliptin.
 - PA all prescriptions, criteria:
 - Require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose failure to reach goal A1C, AND
 - Require the use of concomitant sulfonylurea &/or pioglitazone in patients who have not reached their HbA1C goal with metformin monotherapy, unless contraindicated due to HF, edema, or fracture risk.

***Sitagliptin has the FDA approval to be given with insulin for T2DM. There is no evidence regarding whether sitagliptin with or without insulin results in improved health outcomes. In the company-sponsored trial, sitagliptin + insulin + metformin was "well-tolerated". The A1C was 0.6% less in the sitagliptin group but the insulin arm was fixed.

6

4/3/2011 Proposed criteria for sitagliptin (Januvia) and saxagliptin (Onglyza) or any sitagliptin or saxagliptin-containing product:

1. Deny if any insulin claim in the past 30 days.
2. Continue no monotherapy access for sitagliptin or saxagliptin. Combination products require generic monotherapy prior to access.(i.e. Must fail metformin monotherapy as well as other generic combo therapies prior to getting this nonvalidated therapy.)
3. PA all prescriptions, criteria:
 - require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND then
 - Require the use of concomitant sulfonylurea, unless contraindicated, &/or pioglitazone in patients who have not reached HbA1C goal with metformin monotherapy, unless pioglitazone is contraindicated due to HF, edema, or fracture risk.
 - Prior to access to Kombiglyze XR (saxagliptin + metformin), metformin^b + sulfonylurea + pioglitazone and without saxagliptin must fail to achieve goal HbA1C.
4. No therapeutic duplication with sita- or saxa-gliptin. (Deny the drug if the other is filled in the previous 30 days.)

^aMetformin must be titrated slowly upward. Metformin 500mg twice daily is the initial dose. Patients should increase to at least 850 mg twice daily before determining failure.

^bMetformin must have an adherence rate of 4 of the past 5 months prior to gaining access to sitagliptin or saxagliptin.

References:

¹UKPDS 34. Lancet 1998; 352: 854–65. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 34.pdf>

²UKPDS 33. Lancet 1998; 352: 837–53. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\UKPDS 33.pdf>

³Lincoff AM, et al. **Pioglitazone and Risk of Cardiovascular Events in Patients With Type 2 Diabetes Mellitus A Meta-analysis of Randomized Trials.** *JAMA.* 2007;298(10):1180-1188. <C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\Pioglitazone CV risk reduction-JAMA 07.pdf>

3.c. Symlin and Symlinpen----The Board was interested in developing step therapy criteria for these medications before they agree to exclude from coverage.

Pramlintide (Symlin, Symlinpen)

CURRENT

- No edits

PROPOSED

- Exclude

4/3/11 Proposed Step Therapy:

1. None^a.

^aNo proposed step therapy due to no evidence of reduction in any diabetes related events, an increased risk of severe hypoglycemia when given with insulin, increased risk of nausea (30% of patients), slowed gastric emptying (in patients already at risk for diabetic gastroparesis), and only a 0.7% reduction in HbA1C at best, again without evidence of risk reduction.

DUEC New Drugs Oct-Dec 2010

| Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|-------------------------|---|--|--|---------------------|-------------------------------------|---|--|---|----------------|
| CYCLOSET TAB 0.8MG | BROMOCRIPTINE MESYLATE TAB 0.8 MG (BASE EQUIVALENT) | metformin \$42-\$108 per 30 days, sulfonylureas \$10-\$93, per 30 days | Actos 15-45mg \$173.40--\$287.40 per month, januvia \$226.50 per month | 1.8 per 0.8mg tab | 2- 6 ta/day (\$108-\$324 per month) | Cycloset, an ergot derivative, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Cycloset should not be used as a treatment of type 1 diabetes or diabetic ketoacidosis. There is limited efficacy data for the use of Cycloset in combination use with thiazolidinediones, and efficacy has not been confirmed in combination with insulin. | Cycloset is a novel therapy directly targeting the body's dopamine activity to improve glycemic control. It provides physicians with another treatment option for their patients with type 2 diabetes. • Unlike many other currently available drugs that stimulate insulin release, Cycloset improves glycemic control without increasing circulating insulin levels. | Exclude at this time. Has not been compared to metformin. No outcomes except HbA1C. | |
| KOMBIGLYZE TAB 2.5-1000 | SAXAGLIPTIN-METFORMIN HCL TAB SR 24HR 2.5-1000 MG | Janumet 50-500mg and 50-1000mg 3.77 | \$226.30 per month | 3.67 | \$110.10 per month | For the treatment of type 2 diabetes mellitus in combination with diet and exercise when treatment with both saxagliptin and metformin is appropriate | Tier 3 with step (like Janumet) | T3 with lookback 180d for metformin monotherapy. | |
| KOMBIGLYZE TAB 5-1000MG | SAXAGLIPTIN-METFORMIN HCL TAB SR 24HR 5-1000 MG | Janumet 50-500mg and 50-1000mg 3.77 | | 7.34 | \$220.20 per month | | Tier 3 with step (like Janumet) | " | |
| KOMBIGLYZE TAB 5-500MG | SAXAGLIPTIN-METFORMIN HCL TAB SR 24HR 5-500 MG | Janumet 50-500mg and 50-1000mg 3.77 | | 7.34 | \$220.20 per month | | Tier 3 with step (like Janumet) | " | |
| ELLA TAB 30MG | ULIPRISTAL ACETATE TAB 30 MG | Plan B, Plan B one step, Next Choice | Plan b \$15.88 per tab= \$31.76 per dose, plan B one step \$40.62, Next Choice average generic \$14.62 | 42.90 | | ELLA can be used up to 5 days after unprotected intercourse or a known or suspected contraceptive failure. In comparison, PLAN B and PLAN B ONE-STEP should be used within 3 days per FDA | A disadvantage to ELLA is its Rx-only availability. PLAN B and PLAN B ONE-STEP are available over-the-counter (OTC) for patients > 17 years of age; both are Rx for those < 17 years of age. ► PLAN B is available generically as NEXT . exclude, same as Plan B | Exclude, OTC alternatives | |
| XGEVA INJ | DENOSUMAB INJ 120 MG/1.7ML | Same drug as Prolia, different indications | Prolia 60mg \$990/unit | 1164.71 | \$1165 (120mg every 4 weeks) | For the treatment of osteoporosis in postmenopausal women at high risk for fracture and For the prevention of skeletal-related events in patients with bone metastases from solid tumors | exclude (same as Prolia) | Medical N/A | |
| CARBAGLU TAB 200MG | CARGLUMIC ACID TAB 200 MG | There are 2 currently marketed products known as "nitrogen scavengers," Medicis Pharmaceutical Corp's AMMONUL (sodium phenylacetate/sodium benzoate) and BUPHENYL (sodium phenylbutyrate) approved | Ammonul \$2,866.80 per 50 mL single-use vial Child: \$5,733.60 Adult: \$11,467.20 for 30 day supply. Buphenyl \$7.72 per tablet; \$3,857.38 per 250 gram can Child: \$3,857.38 - | 159.60 | \$5586 per day | CARBAGLU (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated as: (1) adjunctive therapy for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) and (2) maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). | CARBAGLU is the only product FDA-approved as a specific treatment of hyperammonemia due to NAGS deficiency. Other available treatments are unspecific for this indication. | PA T3. Specialty | |
| BROMDAY SOL 0.09% | BROMFENAC SODIUM OPHTH SOLN 0.09% (BASE EQUIV) (ONCE-DAILY) | Xibrom | | 91.18 | 1.700ML | | | | |

| Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|---------------------------|--|--|--------------|---|---|---|--------------------|--------------------|--------------------|
| GILENYA CAP 0.5MG | FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV) | Avonex, Betaseron, COPAXONE, EXTAVIA, NOVANTRONE, REBIF, TYSABRI (vs. \$2,800 - \$3,200 month for injectable therapies) | 158.08 | \$4426 per 28 day supply | GILENYA (fingolimod) is the first oral therapy approved for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. GILENYA belongs to a new class of drugs called sphingosine-1-phosphate receptor (S1P) modulator | Current treatment guidelines recommend that initiation of interferon beta or glatiramer acetate should be considered when a diagnosis of relapsing disease is made. Natalizumab is generally reserved for patients who had an inadequate response or were unable to tolerate other MS therapies. Mitoxantrone is reserved for relapsing patients with worsening disease or patients with secondary progressive disease, whether or not relapses are occurring. first in class drug that prevents white cell release from lymph nodes, which attach the myelin sheath... risk of toxicity for the heart, lung & eye along with increase risk of infection. | T3 w PA. Specialty | T3 w PA. Specialty | T3 w PA. Specialty |
| GLASSIA INJ | PROTEINASE INHIBITOR (HUMAN) INJ 1000 MG/50ML | ARALAST - PROLASTIN -ZEMAIRA - | 11.04 | Single use vial 1 gram Alpha1-PI in 50 mL Solution 60 mg/kg body weight | | | Exclude. Specialty | | |
| BEYAZ TAB | DROSPIRENONE-ETHINYL ESTRAD-LEVOMEFOLATE TAB 3-0.02-0.451 MG | compared to about \$50 for the generic without folate (Gianvi) plus \$2 for a folate supplement | 3.04286 | 85.12 | | Beyaz (bee-YAZ) is a new version of Yaz with folate. recommend using a generic OC plus a separate multivitamin or folic | Exclude | | |
| PEDIADERM TA KIT | *TRIAMCINOLONE CREAM 0.1% & EMOLLIENT CREAM KIT** | | 1.45043 | | | exclude kits | Exclude | | |
| PEDIADERM AF KIT COMPLETE | *NYSTATIN CREAM 100000 UNIT/GM & DIAPER RASH CREAM KIT** | | 1.15833 | | | exclude kits | Exclude | | |

| Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|-----------------------|---|---|--------------|--|--|---|--|-----------------------------------|----------------------------------|
| PRADAXA CAP 75, 150MG | DABIGATRAN ETEXILATE MESYLATE CAP | warfarin \$23/month | 4.05 | \$8.10 per day and/or \$243 per 30 day supply. | PRADAXA is the first oral direct thrombin inhibitor (a type of anticoagulant). It is FDA-approved to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF). PRADAXA will be competing with warfarin (COUMADIN, JANTOVEN), the existing "gold standard" oral anticoagulant that has been on the market for over 50 years. PRADAXA was designed to overcome the disadvantages of warfarin, specifically regarding onset of action and dissipation, predictability of anticoagulant effect, probability of food-drug interactions, and need for monitoring. PRADAXA is also being studied for other conditions such as venous thromboembolism (which will open the market for it to compete against heparin and low molecular weight heparins (LMWH)). | * Significant decrease risk of bleeding complications as compared to warfarin. Cost effectiveness study in the Annals of Internal Medicine supports this. * More predictable anticoagulant action thus less frequent coagulation monitoring & dosage adjustments * More rapid onset and offset of action. * Low risk of drug interactions To mitigate the risks of bleeding associated with the use of PRADAXA, the drug will be subject to a risk evaluation and mitigation strategy (REMS). A Medication Guide will be required to be dispensed along with each prescription informing patients of the serious risks associated with PRADAXA, particularly the increased risk of bleeding and how such symptoms should be recognized. : Cover with a daily dose limit of 2 per day. | T3 | T3 PA: 1. Dx of AF. QL of 62/32d. | T2 PA: 1. Dx of AF. QL of 62/32. |
| AELVIA TAB | RISEDRONATE SODIUM TAB DELAYED RELEASE 35 MG | Actonel 35mg | 30.45 | \$121.76 | | | | T3 | |
| EGRIFTA INJ 1MG | TESAMORELIN ACETATE FOR INJ 1 MG (BASE EQUIV) | | 39.29 | | | | Exclude. Whether Egrifta decreases the risk of cardiovascular disease or improves compliance with antiretroviral drugs has not been studied. | | |
| KRYSTEXXA INJ 8MG/ML | PEGLOTICASE INJ 8 MG/ML (FOR IV INFUSION) | | 1,380.00 | | | | N/A Medical. | | |

DUEC New Drugs Jan-March 2011

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|----------------------------|-----------------------------|---|---|---|-----------------------|-------------|---|--|---|----------------|
| 0250 0030 1021 ** | TEFLARO INJ 600MG, 400mg | CEFTAROLINE FOSAMIL FOR IV SOLN 600 MG | Cubicin/Tyagacil/Vancomycin/Vibativ | NA | 49.2 | NA | Acute bacterial skin and skin structure infectio(SSSI). Community acquired bacterial pneumonia (CABP) including MRSA. | exclude IV | Exclude. This should be an inpatient drug or one supplied by a home infusion company and would be covered by medical. | |
| 8810 9903 4918 20 | FIRST DUKES SUS MOUTHWSH | *DIPHENHYDRAMINE- HYDROCORTISONE- NYSTATIN SUSP*** | available as separate components to compound | \$25-30 | 0.173 | \$41.00 | Treatment of pain/inflammation associated with mucositis caused by radiation therapy or chemotherapy, aphthous and other oral ulcers, and mouth pain. | Each compounding kit is made for one patient and include pre-weighed powders and pre-measured suspension for the pharmacist to reconstitute. alternative to compound RX | T3. Pharmacist-compounded products are reimbursed at the T3 level. A T3 copay would cover this completely as long as \$41 is for a 31 days supply. | |
| 8810 9904 6018 20 | FIRST-MARYS SUS MOUTHWSH | *DIPHENHYDRAMINE- HYDROCORTISONE- NYSTATIN- TETRACYCLINE SUSP** | available as separate components to compound | \$25-30 | 0.18354 | \$43.50 | Treatment of pain/inflammation associated with mucositis caused by radiation therapy or chemotherapy, aphthous and other oral ulcers, and mouth pain. | Each compounding kit is made for one patient and include pre-weighed powders and pre-measured suspension for the pharmacist to reconstitute. alternative to compound RX | T3. Pharmacist-compounded products are reimbursed at the T3 level. A T3 copay would cover this completely as long as \$41 is for a 31 days supply. | |
| 5940 0023 1003 ** | LATUDA TAB 40 80MG | LURASIDONE HCL TAB 80 MG | Abilify/Geodon/Invega/risperidone/Saphris/Seroquel XR/Zyprexa | #330-610 | 16.8 | \$504 | 40-80mg daily for the treatment of schizophrenia in adults. | May offer an early onset of action (3 days). Early data indicates lower weight gain compared to olanzapine. Lacks long-term safety and efficacy data. All the pivotal phase III clinical trials were limited to 6 weeks duration.add to tier 2 | Exclude. Latuda has only 4 six-week placebo controlled trials. There is no evidence for superiority because it has not been compared to any active controlled use where the trial was powered to find any clinical difference. Re-search the literature in 6 months for comparative data. | |
| 4910 2030 0020 60 | CUVPOSA SOL 1MG/5ML | GLYCOPYRROLATE ORAL SOLN 1 MG/5ML | GLYCOPYRROLATE tablet 1 and 2mg | \$1.05/1MG TAB | 0.95 or \$4.75/5ml | | For the reduction of severe chronic drooling in patients with neurologic conditions associated with drooling (e.g., cerebral palsy). Dosage: Children/adolescents max dose: 0.1mg/kg/dose TID | Only oral solution available but generic 1mg tab available | T3 | |
| 3620 1010 1011 20 | NEXICLON XR SUS 0.09/ML | CLONIDINE HCL EXTENDED RELEASE SUSP 0.09 MG/ML (BASE EQUIV) | Jenloga/Kapvay/clonidine/Catapres TTS | 30 mday supply:: Clonidine IR- \$33;Kapvay XR-\$151; Catapres TTS-\$95 | 2.44068 | \$366/mo | Dosage: 0.17mg daily at bedtime for hypertension. Max dose is 0.52mg/day. | Extended release oral suspension form; exclude-generic available | Exclude; IR tablets can be crushed. Extemporaneously prepared 0.1mg/mL oral suspension may be made from tablets. Directions in LexiComp. This clonidine is for HTN. | |
| 3620 1010 1075 10 | NEXICLON XR TAB 0.17MG | CLONIDINE HCL TAB SR 24HR 0.17 MG (BASE EQUIVALENT) | Jenloga/Kapvay/clonidine/Catapres | 30 mday supply:: Clonidine IR- \$33;Kapvay XR-\$151; Catapres TTS-\$95 | 4.8 | \$288/mo | Dosage: 0.17mg daily at bedtime for hypertension. Max dose is 0.52mg/day. | exclude-generic available | Exclude. This clonidine is for HTN. | |

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|----------------------------|------------------------------|--|---|---|---------------------|--|--|---|--|----------------|
| 6260 9902 3001 20 | NUEDEXTA CAP 20-10MG | DEXTROMETHORPHAN HBR-QUINIDINE SULFATE CAP 20-10 MG | NA | 9.78 | \$586.80 | One 20/10mg tablet daily for 7 days then increase to one tablet every 12 hours for the treatment of pseudobulbar affect(PBA) | This combo first FDA approved treatment for PBA occurs secondary to various unrelated neurological conditions and is characterized by uncontrollable episodes of laughing and/or crying. cover with QL of 2 per day | T3 with PA. 1. Dx of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS), and 2. Dx of clinically significant Pseudobulbar Affect (PBA) (a baseline score ≥13 on the Center for Neurologic Studies-Lability Scale [CNS-LS]). (not effective for heroin detox). The quinidine increases dextromethorphan's bioavailability by 20-fold. The dextromethorphan is what treats the disease. | | |
| 6020 4080 1020 20 | ZOLPIMIST SPR 5MG | ZOLPIDEM TARTRATE ORAL SPRAY 5 MG/ACT | Ambien,Ambien CR, Edluar. | 30 day supply: \$204-385 | 9.35065 | \$72.00 | 10mg (2 sprays) PO immediately before bedtime. | Oral spray dosage form.exclude-generic available | Exclude | |
| 8610 1038 1020 25 | MOXEZA SOL 0.5% | MOXIFLOXACIN HCL OPTH SOLN 0.5% (BASE EQ) (2 TIMES DAILY) | Vigamox | \$30.58/ML \$92.00/7 DAY | 30.58 | \$92.00/7 DAYS | One drop in each affected eye BID for 7 days for bacterial conjunctivitis. | Moxeza needs only to be administered twice daily vs Vigamox TID.add to tier 3 (same as Vigamox) | Which tier is Vigamox? (place at same tier; negotiate for T2 if rebates available) Moxeza provided total peak and superior exposure vs Vigamox. Whether this translates into cost-effective medication | |
| 6420 0010 0020 70 | OFIRMEV INJ 10MG/ML | ACETAMINOPHEN IV SOLN 10 MG/ML | NA | 0.129 | | | Intravenous acetaminophen (Ofirmev) approved for the treatment of pain/fever in adults and children over the age of 2 years.Adults,Adolescents 50kg or greater: 1000mg IV every six hours or 650mg IV every 4 hours as needed. | Exclude-generic available and IV dosage form | Exclude. IV; not outpatient drug. | |
| 2599 0003 2003 30 | SAFYRAL TAB | DROSPIRENONE-ETHINYL ESTRADILEVOMEFOLATE TAB 3-0.03-0.451 MG | Beyaz \$85.12 per month | 3.04286 | \$85.12 | Indicated for pregnancy prevention and to raise folate levels in women who want to use an oral contraceptive for contraception.One tablet PO daily following in order directed on package. | recommend using a generic OC plus a separate multivitamin or folic acid supplement | Exclude; consider reference pricing with all OC's. | | |
| 8510 0010 2664 70 | XYNTHA INJ 3000UNIT | ANTIHEMOPHILIC FACTOR RECOMBINANT PAF FOR INJ KIT 3000 UNIT | Kogenate, Humate, Alphante | \$0.50-\$2.17/unit 3000units/\$3,600-\$%,040 | 1.66 | 3000 units = \$4,980 | Hemophilia | Antihemophilic factors covered with PA at Ascend | Specialty. T3 PA. | |
| 3699 6803 2003 20 | AMTURNIDE150 TAB -5-12.5 | ALISKIREN-AMLODIPINE-HYDROCHLOROTHIAZIDE TAB 150-5-12.5 MG | Tekturma HCT and amlodipine | Tekturma HCT 3.21 | 2.976 | \$89.28 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 3699 6803 2003 40 | AMTURNIDE300 TAB -10-12.5 | ALISKIREN-AMLODIPINE-HYDROCHLOROTHIAZIDE TAB 300-10-12.5 MG | Tekturma HCT and amlodipine | Tekturma HCT 4.25 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|----------------------------|--|---|---|--|---------------------|--------------------|---|---|---|----------------|
| 3699 6803 2003 45 | AMTURNIDE300 TAB -10-25MG | ALISKIREN- AMLODIPINE- HYDROCHLOROTH AZIDE TAB 300-10- 25 MG | Tektuma HCT and amlodipine | Tektuma HCT 4.34 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 3699 6803 2003 30 | AMTURNIDE300 TAB -5-12.5 | ALISKIREN- AMLODIPINE- HYDROCHLOROTH AZIDE TAB 300-5- 12.5 MG | Tektuma HCT and amlodipine | Tektuma HCT 4.06 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 3699 6803 2003 35 | AMTURNIDE300 TAB -5-25MG | ALISKIREN- AMLODIPINE- HYDROCHLOROTH AZIDE TAB 300-5-25 MG | Tektuma HCT and amlodipine | Tektuma HCT 4.34 | 3.756 | \$112.68 | Hypertension | * Dose consolidation that can lead to improved adherence rates. add to tier 3 with ST | T3 with ARB ST. | |
| 6510 0025 1007 ** | ABSTRAL SUB 100MCG, 200, 400, 600, 800 | FENTANYL CITRATE SL TAB 100 MCG (BASE EQUIV) | Fentora, Onsolis, Fentanyl, Actiq | 22.58-59.76 100 to 800mcg for Fentora, 23.33-67.08 Onsolis 45-150 for actiq, 18.80 -\$55.43 for generic Actiq | 16.8- 48 | | Abstral is indicated for the management of breakthrough pain in patients with cancer, ages 18 years and older, who already use opioid pain medication around the clock and who need and are able to safely use high doses of an additional opioid medicine. | Abstral is available only through a Risk Evaluation and Mitigation Strategy (REMS) program, which is intended to minimize the risk of misuse, abuse, addiction and overdose. Under this program, pharmacies, distributors, and health care professionals who prescribe to outpatients are required to enroll in the program to prescribe, dispense and distribute this product. | T3 PA. QL of 4 tabs/1 day or 120/30d. PA criteria: 1. Dx of cancer AND on who are taking at least 60 mg of oral morphine/daily, or at least 25 mcg transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg oral hydromorphone daily, at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. ABSTRAL is indicated only for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. | |
| 2310 0030 0040 70 | FORTESTA GEL 10MG/ACT | TESTOSTERONE TD GEL 10MG/ACT (2%) | Androgel , Testim, Androderm | Androgel \$333.00, Androderm \$325 | 5.01483 | \$300 per 60gm | Hypogonadism | Androgel, Testim and Androderm tier 2 with PA | T3, PA: 1. Dx of testosterone deficiency in males OR hypogonadism or hypogonadotropic hypogonadism in males OR delayed puberty in males. (We should select one testosterone topical and negotiate for rebates.) | |
| 9090 0048 0018 20 | NATROBA SUS 0.9% | SPINOSAD SUSP 0.9% | Lindane lotion, shampoo-\$15-\$91 Elimite \$79.80 | Pronto OTC \$12 | 1.99 | \$238.80/4 oz | Head Lice | exclude, less expensive options available | T2 w/ ST: Require 2 fills of permethrins in the past 30 days. (Permethrins is 1st line tx by the American Academy of Pediatrics). | |
| 4399 5803 75** | PROHIST CD LIQ | PHENYLEPH- TRIPROLDINE- CHLORPHEDIANOL 10-2.5-25MG/5ML | Brotapp DM, C- Phen | \$0.04/ml \$4.80/120ml | 0.18867 | \$22.64/12 0ml | Antitussive/Decongestant/A ntihistamine | Multiple generics available - exclude | Exclude. Generic alternatives. Not in Drug Facts and Comparisons. Accessed 3/28/11. | |
| 4399 5702 0709 ** | PROHIST CF LIQ | CHLORPHEDIANOL- TRIPROLDINE 25- 2.5MG/5ML | Promethazine DM | \$0.04/ml \$4.80/120ml | 0.18867 | \$22.64/12 0ml | Antitussive/Antihistamine | Exclude- generic available | Exclude. Generic alternatives. Not in Drug Facts and Comparisons. Accessed 3/28/11. | |
| 4399 3002 8309 ** | PROIHIST LQ LIQ | TRIPROLDINE- PHENYLEPHRINE LIQ 2.5-10MG/5ML | Triproline/PSE syrup | \$0.64/ml \$7.68/120ml | 0.18867 | \$22.64/12 0ml | Antitussive/Low sedating antihistamine | Exclude - generic available | Exclude. Generic alternatives. Not in Drug Facts and Comparisons. Accessed 3/28/11. | |
| 906 600 800 000 | ALUVEA CRE 39% | UREA 39% | Urea 50% cream | \$1.12/gm \$159.00/142gm | 1.5806 | \$224.36/1 42gm | Dystrophic nail removal , mild kerosis, keratolytic | exclude-generic available | exclude. Generics available. | |

| GPI | Drug | Generic Name | Other Drugs in Same Class (AWP Pricing) | AWP per unit | Estimated AWP/month | Indications | PBM Notes | Consultant's Notes | DUEC Vote | Insurance Vote |
|--------------------------|----------------------|---------------------------|---|------------------------------------|--------------------------------|--|--|---|---|----------------|
| 906 600 800 007 | ALUVEA CRE 43% | UREA 43% | Urea 50% cream | \$1.12/gm \$159.00/142gm | 1.5806 | \$224.36/142gm | Dystrophic nail removal , mild kerosis , keratolytic | exclude-generic available | exclude. Generics available. | |
| 361 500 102 003 | EDARBI 40MG | AZILSARTAN MEDOXOMIL 40MG | Cozaar,Atacand,Diovan,Avapro, Losartan,Micardis,Teveten,Benicar | \$90-114/month | 2.94 | \$88.20 | ARB-hypertension | Tier 3 with step therapy | T3 ARB ST | |
| 361 500 102 003 | EDARBI 80MG TAB | AZILSARTAN MEDOXOMIL 80MG | Cozaar,Atacand,Diovan,Avapro, Losartan,Micardis,Teveten,Benicar | \$90-114/month | 2.94 | \$88.20 | ARB-Hypertension | Tier 3 with step therapy | T3 ARB ST | |
| | Kapvay 0.1 mg tablet | clonidine XR | clonidine 0.1mg tab, MAC=\$0.04 | \$2 | AWP per tab = \$2.52 | \$151 | | | This clonidine is for ADHD. Exclude. This is administered BID like the IR except it is not interchangeable. PI states longterm use (>5w) has not been studied. In 1 trial vs placebo, it was superior to placebo @5w. | |
| | Axiron Soln | Testosterpme TD Soln | Androgel , Testim, Androderm | Androgel \$333.00, Androderm \$325 | \$3.71 | \$334.32/90ml | Hypogonadism | Androgel, Testim and Androderm tier 2 with PA | | |
| | Benlysta inj | Belimumab IV soln | | | \$531/120mg \$1772.71/400mg | For tx of active, autoantibody-positive, systemic lupus erythematosus (SLE) in combination with standard therapy | 10m/kg/dose IV every 2 weeks for the first 3 doses then every 2 weeks thereafter. Only healthcare providers prepared to manage anaphylaxis should administer Benlysta. | No peer-reviewed trials in pubmed. From PI, did not work in Blacks. Mortality was higher with the drug than with placebo. Only worked in auto-antibody positive patients. | | |