TMA DoD Pharmacoeconomic Center
Fort Sam Houston, TX

MTF Quarterly Webcast
March 14, 2013

Introduction

- Greetings from the PEC
- Purpose of the Quarterly MTF Webcast
- DCO Ground Rules
  - Type questions into the DCO system
  - Put on mute, not on hold
  - Contingency plan if DCO system stops working

Outline

- Data Integrity– Update from the Pharmaceutical Operations Center
- Review of November 2012 P&T Committee Meeting
- Overview of February 2013 P&T Committee Meeting
- Quick Look at May 2013 P&T Committee Meeting
- Miscellaneous issues
- Questions

MTF Corner

Data Integrity Brief

Rosemary Gonzalez
TMA Pharmacy Operations Center

Agenda

1. How PDTS works with CHCS
2. Days Supply
3. High Dose Alert
4. Edit/Modify Non compliant functionality
5. Data Integrity Issues
6. Data Integrity Reports

Pharmacy Data Transaction Service (PDTS)

PDTS Functions

- PDTS establishes a DoD data repository by creating and maintaining patient prescription profiles for all points of service
- Allows DoD to improve the quality of its prescription service and reduce pharmaceutical costs
- The central data repository also allows DoD to monitor and track patient usage and provider prescribing patterns throughout the MHS

How PDTS works with CHCS

How does the quantity & package size work together in PDTS?

When the User enters the quantity for the prescription in CHCS, that number is multiplied by the package size and sent to PDTS.

Example of Correct quantity & price processed in PDTS

Drug: Lancets package size 200
Correct qty 400
Qty field 2 x 200 = 400 (if package size is populated with 200)
Correct Price $19.98
400 x 0.04995 = $19.98

Example of an Incorrect quantity & price processed in PDTS

Drug: Lancets package size 200
Qty processed by PDTS 80,000 (package size field is populated with 200)
Qty field 400 x 200 = 80,000
Price processed by PDTS $ 3,996.00
Price per lancet is $0.04995
0.04995 x 80,000 = $3,996.00

Days Supply & High Dose Alert

When a user enters the days supply for a prescription in CHCS that number is sent to PDTS, if the days supply is lower than the maximum daily dose set in PDTS, a HIGH Dose Alert (DUR) will be generated . If the days supply field is left blank, the prescription will reject in PDTS and a clinical screen will not occur.

Example of transaction sent to PDTS with a missing days supply.
Drug : Acetaminophen Liquid 160mg/ 5ml
Qty 120
Days Supply 0
PDTS Reject Code MI DAYS SUPPLY

POC will contact the MTF pharmacy and verify correct days supply and reprocess the prescription .

Edit/Modify & Non-Compliant Functionality

Edits

- Edits made to prescriptions in CHCS in the following fields Provider, NDC, Quantity and Days supply will send the corrections to PDTS
- Edits made to the drug file will not fix the quantity or NDC issues on the actual prescription.

  Example

  Package size is edited in the drug file, the actual prescription will need to be edited and resubmitted to PDTS

Modify

- When a prescription is modified , a message is sent to PDTS.

  The original prescription is not reversed (as it may have been dispensed) and will remain on the patient's PDTS profile.

  A new Rx number in PDTS will be assigned to the prescription modified

Non-Compliant

- In 2007 an Automated Non-Compliant functionality was created to automate the marking of appropriate fills non-compliant in CHCS. Marking the prescription non-compliant will remove the fill from PDTS profile.

Data Integrity issues

How do Data Integrity Issues occur?

- User is unaware that the package size field is populated with the drug 's package size or unit of measure
- NDC number is not in first Data bank
- Missing days supply, date of birth or gender code
- Enters a partial fill incorrectly or the attempts to forward the partial fill to another pharmacy failed . Missed critical fields when building a compound medication recipe
- When a user enters a partial quantity, the quantity partialed plus the completed quantity should equal the intended quantity.

A clinical screening will not be processed by PDTS for prescriptions that are transmitted with the issues listed above , only a local CHCS clinical screening will be processed.

Types of Data Integrity Reports

High Dose Alert Report-

This report captures prescriptions that either have an incorrect day supply, incorrect quantity or both.

Pharmacy Name	Date Dispensed	Rx #	Date Written	Drug/Strength/Form	NDC	Metric Quantity	Days Supply	DS/MQ
BRAGG ONC NEW WAMC PHCY	2/6/2013	2192654	2/6/2013	ABIRATERONE ACETATE 250 MG TABLE	57894015012	14,400.00	30	MQ
ELMENDORF PHCY	2/5/2013	2769721	2/5/2013	ACETAMINOPHEN 100 MG/ML DROPS	00603083873	15	1	DS

Reasons for reporting

- ✓ Provider has no visibility of the number in the day supply field.
- ✓ Pharmacy missed the incorrect days supply
- ✓ Days Supply is correct, yet it is greater than the max days set for the daily dose in PDTS.
- ✓ Prescriptions for deployment that exceed 30 days supply.

Note: We request that when the POC for the Data Integrity Reports is or has PCS'd, ETS'd or left your Pharmacy, let us know who their replacement is.

Types of Data Integrity Reports Cont'

Over $ 2000 Report

This report captures prescriptions that may have an incorrect days supply , quantity, price and each prescription has a total submitted amount of $2,000 or more.

Pharmacy Name	Rx #	Drug/Strength/Form	NDC	Date Written	Date Dispensed	Quantity Dispensed	Correct Metric Qty	Days Supply	Date Processed	Total Submitted Amount Due
BRAGG OP NEW WAMC PHCY	000002261331	GLATIRAMER ACETATE 20 MG/ML SYRINGEKIT	68546031730	2/27/2013	2/27/2013	30		30	2/27/2013	$56,572.76
PORTS VA BHC OCEANA	000006216271	BLOOD SUGAR DIAGNOSTIC STRIP	57599969405	2/5/2013	2/27/2013	40,000		100	2/27/2013	$9,247.67
MOODY PHCY 23RD MDG	000001234796	LIDOCAINE 5%(700MG) ADH. PATCH	63481068706	2/25/2013	2/27/2013	900		30	2/27/2013	$3,962.83

Types of Prescriptions captured

- ✓ Prescription may be a legitimate high dollar prescription (antineoplastics , hormones)
- ✓ Pharmacy has incorrect price in the Local Cost Filed

Note: We greatly appreciate that corrections to the Over $ 2000 report be sent back to us by Thursday of each week.

Incorrect Quantity

Example of incorrect quantity transmitted to PDTS due to Unit of measure vs. 30 inhalation units.

Drug: ASMANEX AER POW BA
NDC # 00085-1461-02
Fill date : 3/15/2010
Qty 30 = 30 canisters (package size filed is blank) (Correct qty 1)
D/S 30
Refill code 0
U/M EA
Package Description: Canister
Package Size 1
Local Cost flag on No
Cost $5551.20 (30 x 185.04= 5551.20) (Correct cost $ 185.04)

Incorrect Pricing in PDTS

Example of incorrect pricing when the transaction is processed to PDTS with an incorrect price set in the local cost flag field.

Drug: ADVAIR DISKUS
NDC # 00173-0696-00
Fill date : 3/18/2010
Qty 60
D/S 30
Refill code 0
U/M EA
Package Size 60
Package Description: BLIST PACK
Local Cost flag on Yes $82.80 (price set in CHCS per entire container)
Cost $4,968.00 (60 X $82.80=$4,968. 00) correct price (60X 1.50= $90.00 price per each blister pack)

Questions?

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Review of November 2012 P&T Committee Meeting

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November 2012
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Non-Insulin Diabetes Drugs: Glucagon Like Peptide-1 Receptor Agonists (GLP-1)
  - Overactive Bladder Class
  - Gastrointestinal Antibiotics (GI-2) Class
  - Hepatitis C Drugs
- **New Drugs in Previously Reviewed Classes**
  - Oxycodone Immediate Release (Oxecta)

November 2012
DoD P&T Committee Meeting

- **Utilization Management**
  - NF to UF Changes When Cost Effective Generics Available – escitalopram (Lexapro) and pantoprazole (Protonix)
  - PA Changes
    - PDE-5 post prostatectomy
    - Testosterone use in women
    - Fertility Drugs
  - PA/QL
    - adalimumab (Humira) for ulcerative colitis
    - enzalutamide (Xtandi) for prostate cancer
    - abiraterone (Zytiga) for prostate cancer
  - QL
    - ipratropium/albuterol inhaler (Combivent Respimat)
    - azelastine/fluticasone nasal spray (Dymista)

Uniform Formulary Class Reviews

GLP-1 Subclass

Drugs in the Class

Active Ingredient	Brand (Mfg)	Administration	Strengths	FDA Approval Date
Exenatide	Byetta (Amylin)	BID	5 mcg – 300 mcg/1.2mL 10 mcg – 600mcg/2.4mL	04/28/2005
Exenatide once weekly	Bydureon (Amylin)	Q week	2 mg/0.65mL (3.08 mg/mL)	01/27/2012
Liraglutide	Victoza (Novo Nordisk)	QD	0.6mg, 1.2mg, 1.8mg 18mg/3mL	01/25/2010

-Currently require trial of metformin/sulfonylurea prior to a GLP-1RA
-Byetta is preferred over Victoza

GLP-1 Clinical Conclusion

- Treatment guidelines focus on a patient-centered approach to therapy and treatment goals
- Metformin is the most cost-effective agent and remains the first line treatment in all patient, unless contraindications exist, due to positive outcomes data from UKPDS
- When used as monotherapy or in combination with other oral agents, GLP1RAs decrease A1c ~ 1-2% from baseline
- When compared head to head, there are no clinically relevant differences between GLP1RAs in terms of effect on glycemic control
- One head to head study showed clinically superior control with Bydureon vs. Byetta, however, limitations in study design exist
- Bydureon and Victoza have more of an effect on FPG than PPG due to a longer duration of action whereas Byetta has a greater effect on PPG

PPG: postprandial glucose; FPG: fasting plasma glucose

GLP-1Clinical Conclusion

- GLP1RAs when used as monotherapy or as an add-on agent can provide a 2-3 kg weight loss
- GLP1RAs have little effect on or may improve lipid parameters
- GI side effects are the most common adverse events with GLP1RAs
- Bydureon has a lower incidence of nausea (14.4%) compared to Victoza (20.7%) or Byetta (34.7%)
- Injection site reactions were more common with Bydureon (17.1%) than Byetta (12.7%), insulin glargine (1.8%) or placebo (6.4-13%)
- The reported incidence of hypoglycemia in GLP1RAs is low; however, incidence is higher when used with a sulfonylurea
- All agents may produce antibodies however most patients' glycemic control is unaffected

GLP-1 Clinical Conclusion

- Bydureon and Victoza have a BBW for patients with a personal or family history of medullary thyroid carcinoma or in patients with MEN2
- All GLP1RAs may increase the risk of pancreatitis and all should be used with caution in patients with renal impairment
- Bydureon offers additional patient convenience given its once weekly dosing regimen
- There are no published trials that assess long-term outcomes; however the LEADER and EXSCEL studies evaluating long-term cardiovascular safety are currently ongoing

BBW: Black Box Warning; MEN2: Multiple endocrine neoplasia type 2

GLP-1 Final Decision

- Byetta, Victoza, and Bydureon designated Uniform Formulary
- No product selected for BCF
- Removed the current sub-class step (Byetta is no longer the preferred GLP-1product)
  - Metformin or sulfonyurea remain as a requirement prior to trying a GLP-1
  - Unless hx/o adverse event, contraindication, or inadequate response to metformin/SU
- Implementation: March 20, 2013

GLP-1 Final Decision

BCF Medications	UF Medications	NF Medications	Comments
None	▪ exenatide BID injection (Byetta) ▪ exenatide once weekly injection (Bydureon) ▪ liraglutide once daily injection (Victoza)	None	▪ Current requirement for trial of metformin or a sulfonylurea prior to a GLP1RA still applies ▪ Byetta is no longer the preferred GLP1RA (the previous step therapy requiring use of Byetta prior to another GLP1RA has been removed)

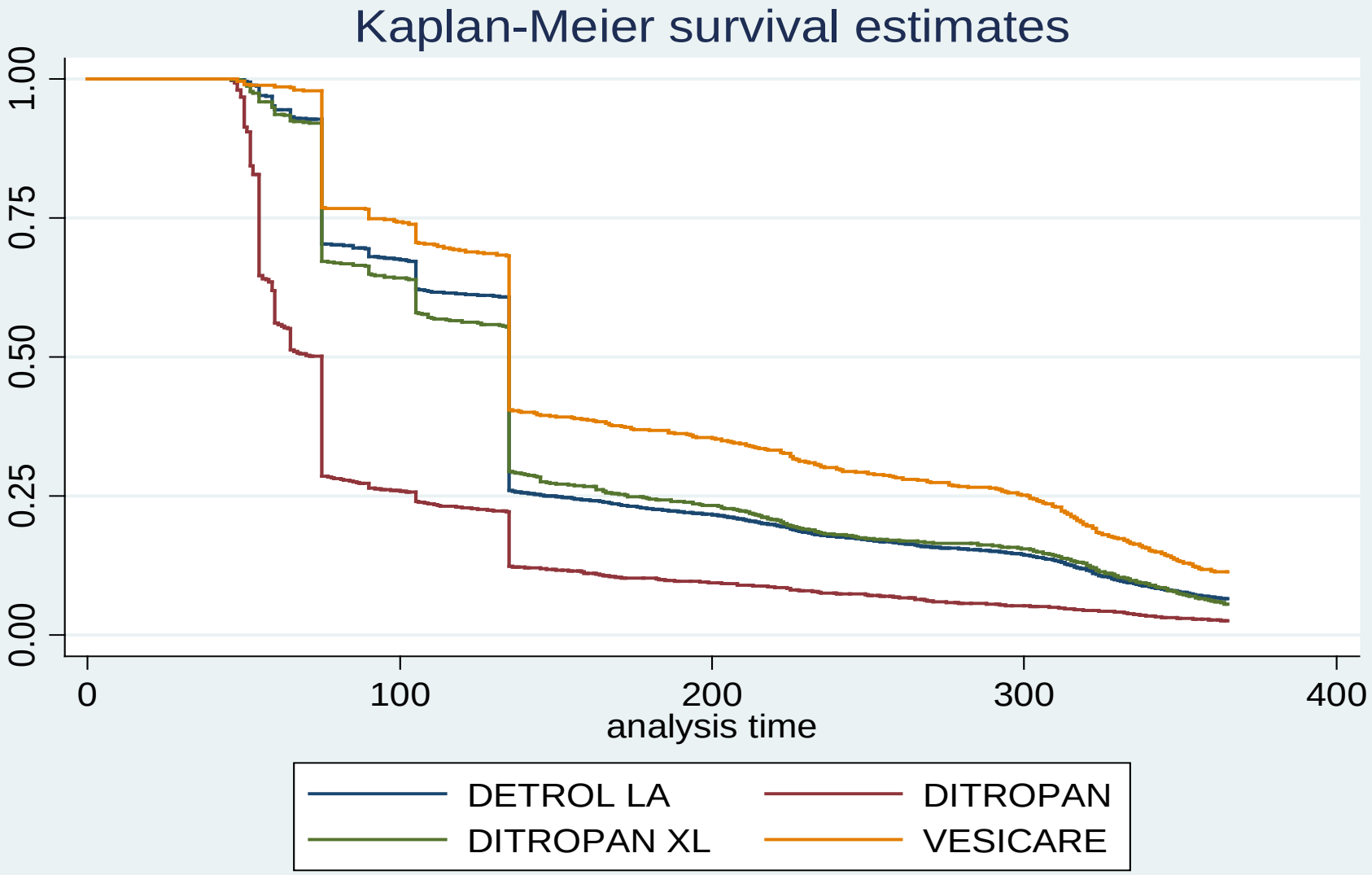
Overactive Bladder (OAB) Class

Drugs in the Class

Generic Name	Brand (Manufacturer)	Generics	Patent Exp
Oxybutynin chloride IR	Ditropan	multiple	-
Oxybutynin chloride ER	Ditropan XL (Ortho-McNeill)	multiple	-
Tolterodine tartrate IR	Detrol (Pfizer)	July 2012	-
Tolterodine tartrate ER	Detrol LA (Pfizer)	No	2014
Oxybutynin transdermal	Oxytrol (Watson)	No	2015
Trospium chloride IR	Sanctura (Allergan)	multiple	-
Solifenacin succinate	Vesicare (Astellas)	No	2018
Darifenacin hydrobromide	Enablex (Novartis)	No	2015
Trospium chloride ER	Sanctura XR (Allergan)	Oct 2012	-
Fesoterodine fumarate	Toviaz (Pfizer)	No	2019
Oxybutynin chloride 10% gel	Gelnique (Watson)	No	2020

-Mirabegron (Myrabetriq) – β-3 agonist will review as a new drug

OAB Persistence – MTF



Persistence rates are low in MHS (12% overall)

OAB Clinical Conclusion

- OAB agents are statistically superior to placebo
  - High placebo rates (30-50%) for the class
- Insufficient evidence to suggest if one agent is superior to another
  - Several meta-analyses show ER drugs superior to IR agents
  - Oxybutynin efficacy similar to tolterodine
  - Newer agents appear to have similar efficacy to older agents
    - Small studies of low quality evidence
      - Fesoterodine statistically superior to Tolterodine
      - Solifenacin statistically superior to Tolterodine
      - Clinical effect is small (~1/day reduction urge/incontinence)
    - Insufficient evidence to draw conclusions for other comparisons
- Not clear if benefits are sustained long-term

OAB Clinical Conclusion

- No single agent with superior profile
  - Oxybutynin IR highest rates of withdrawals and dry mouth
  - Oxybutynin patch has less dry mouth than tolterodine ER, but higher withdrawal rates
- Adverse events lower with ER than IR formulations
- Newer agents do not have significantly lower incidence of dry mouth or constipation
- All agents may cross the BBB resulting in significant CNS effects; decreased potential with trospium
- No studies evaluating clinical outcomes (reduced fall risk; delayed nursing home placement)
- High degree of interchangeability

OAB Final Decision

- BCF:
  - Detrol LA, oxybutynin ER
- UF step preferred (in-front of the step):
  - Detrol LA, oxybutynin ER, oxybutynin IR
  - Trial of one of these 3 drugs required prior to receiving the non-preferred drugs, unless hx/o inadequate response, intolerable adverse event, or contraindication
- UF behind the step (non-preferred):
  - Sanctura IR (generic), Sanctura ER (generic), Detrol IR (generic), Vesicare
  - When the 3 generics are cost-effective, will move in front of step
- NF behind the step (non-preferred)
  - Toviaz, Enablex, Oxytrol patch, Gelnique 10%
- **No grandfathering for step therapy** – All current and new users must try the preferred drug first
- Only usage for OAB allowed or neurological conditions (spina bifida)
- Implementation May 15, 2013

OAB Final Decision

BCF Medications	UF Medications	NF Medications	Comments
▪ Detrol LA* ▪ Oxybutynin ER (Ditropan XL, generics)* *step-preferred	▪ oxybutynin IR (Ditropan, generics)* ▪ Vesicare ▪ trospium IR (Sanctura, generics) ▪ trospium ER (Sanctura ER, generics) ▪ tolterodine IR (Detrol IR, generics) *step-preferred	▪ Toviaz ▪ Enablex ▪ Oxytrol patch ▪ Gelnique	▪ When generic formulations of trospium IR (Sanctura), trospium ER (Sanctura ER), and tolterodine IR (Detrol) become cost effective relative to the step-preferred drugs, they will become step- preferred

Gastrointestinal Antibiotics (GI-2) Class

Drugs in the Class

Active Ingredient	Brand (Manufacturer)	Strengths	FDA Approval Date
Metronidazole	Flagyl and Flagyl ER (Pfizer)	250mg, 375mg, 500mg, 750mg ER	July 18, 1963
Vancomycin	Vancocin (Viro Pharma)	125mg, 250mg	April 15, 1986
Rifaximin	Xifaxan (Salix)	200mg, 550mg	200 mg May 25, 2004 550 mg - March 24, 2010
Fidaxomicin	Dificid (Optimer)	200mg	May 27, 2011
Nitazoxanide	Alinia (Romark)	500mg, 100mg/5mL	July 21, 2004
Neomycin Sulfate	Neo-Fradin (X Gen Pharms) Neomycin (Teva)	EQ 87.5mg/5mL, 500mg	EQ 87.5mg/5mL -2002 500 mg –1964

Analysis by Different Indications

- Hepatic Encephalopathy
- *Clostridium difficile* Infection
- Travelers' Diarrhea
- Off-label uses: Irritable Bowel Syndrome

Hepatic Encephalopathy (HE)

- Guidelines recommend lactulose as 1st-line therapy for hepatic encephalopathy
- A Cochrane analysis found antibiotics superior to non-absorbable disaccharides in improving HE
- Rifaximin is effective in preventing first breakthrough episode of HE vs. placebo
- Rifaximin may reduce frequency of hospitalization in patients with $\geq$ 2 episodes of HE vs. placebo
- While rifaximin is approved for monotherapy, it is commonly used in combination with lactulose
- Rifaximin is better tolerated than lactulose

Clostridium difficile (CDI)

- Decreasing the use of high-risk antimicrobials is associated with a decreased CDI incidence
- IDSA/SHEA guidelines recommend using metronidazole for mild to moderate CDI and oral vancomycin for severe CDI
- Metronidazole was equally effective as vancomycin in treating mild to moderate CDI
- In one study, for mild to moderate CDI, metronidazole and vancomycin were equally effective, but with severe CDI a higher clinical cure rate is seen with vancomycin
- In a small number of study subjects, rifaximin and vancomycin were equally effective for initial response
- Fidaxomicin and vancomycin provided similar clinical cure rates, however fidaxomicin decreased recurrence and increased global cure rates more than vancomycin

Travelers' Diarrhea (TD)

- IDSA guidelines recommend FQs (levofloxacin, ciprofloxacin) as 1st–line treatment, unless contraindications exist
- Antibiotic treatment shortens the duration of TD symptoms from 59 –93 hours to about 1 day
- Rifaximin is only approved for treatment of TD caused by noninvasive strands of *E. coli* and is not effective for *Campylobacter, Shigella*, and *Salmonella* species
- A systematic review found ciprofloxacin more effective than rifaximin for prevention of TD
- Although routine prophylaxis is not recommended in all patients, some military theater locations may warrant use

Off-Label Uses: Rifaximin

Irritable Bowel Syndrome (IBS)

- Guidelines recommend individualized treatment including antispasmodics, laxatives, and $5HT_3$ receptor antagonists
- IBS patients exhibit much inter-patient variability with regard to symptoms, making it difficult to predict who may respond to rifaximin
- In 2 studies, rifaximin showed modest (9-12%) improvements in response rate compared to placebo; however there was a significant placebo effect
- FDA denied approval of rifaximin for IBS in March 2011
- Unanswered questions for rifaximin for IBS include the durability of response, efficacy for retreatment, prevention of recurrence, *C. difficile* emergence, bacterial resistance, and side effects
- At this time, there is insufficient evidence to support use of rifaximin in patients with IBS

Other off-label uses (rosacea, chronic abdominal pain, dyspepsia, ulcerative colitis, inflamm bowel dz, Crohn's dz): unsupportable

GI-2 Oral Abx: Final Decisions

- BCF: metronidazole 250mg & 500mg tabs
- UF: vancomycin, metronidazole 750 mg ER tabs, neomycin, Xifaxan, Dificid, and Alinia
  - Dificid not available at the MTFs or Mail Order; only available at Retail due to Non-TAA compliance
  - Dificid quantity limit of 20 tablets with no refill
- NF: N/A
- Prior Authorization
  - Rifaximin
    - 550 mg allowed for hepatic encephalopathy
    - 200 mg tabs allowed for *E. coli* traveler's diarrhea (must try FQ 1st)
      - Unless <18 years of age, allergy to FQ, returning from area with high FQ-resistance
      - Quantity limit of 9 tablets (3-days supply)
        - **Other uses of rifaximin are not covered**
          - **Implementation May 15, 2013**

Gastrointestinal Antibiotics (GI-2) Class Final Decision

BCF Medications	UF Medications	NF Medications	Comments
▪ metronidazole 250 mg & 500 mg tabs	▪ fidaxomicin (Dificid) ▪ metronidazole 375 mg, 750 mg ER tabs ▪ neomycin ▪ nitazoxanide (Alinia) ▪ rifaximin (Xifaxan) ▪ vancomycin 125 mg, 250 mg oral tabs (Vancocin, generics)	N/A	▪ PA recommendation for rifaximin, limiting use to hepatic encephalopathy (365 days) & traveler's diarrhea (3 days) ▪QLs ▪ fidaxomicin: #20 tabs; no refill ▪ rifaximin 200 mg : #9 tabs; no refills ▪ Dificid not available at Mail Order or MTFs

Hepatitis C Drugs

Drugs in the Class

Generic	Brand (Manufacturer)	Initial FDA approval
Direct-Acting Agents		
Boceprevir	Victrelis (Merck)	5/13/11
Telaprevir	Incivek (Vertex)	5/23/11
Interferons		
PEG Interferon alfa-2A	Pegasys (Genentech)	11/16/02
PEG Interferon alfa-2A; Ribavirin	PEG Interferon (Genentech)	6/4/04
Interferon alfa-2B	Intron A (Merck)	6/4/86
PEG Interferon alfa-2B	PEG Intron (Merck)	1/19/01
PEG Interferon alfa-2B; Ribavirin	PEG Intron/Rebetol Combo Pack (Merck)	6/13/08
Interferon-alphacon-1	Infergen (BI)	10/6/97
Ribavirins		
Ribavirin	Rebetol (Merck); Copegus (Genentech); Ribasphere/Ribapak (3Rivers); other generics	1998

Clinical Conclusions

- Early treatment of Chronic Hepatitis C is associated with higher SVR than later treatment.
- Triple therapy with a direct-acting agent (boceprevir or telaprevir), PEG interferon, and ribavirin increased sustained viral response (SVR) rates to a greater extent than dual therapy with PEG-inteferon and ribavirin (PR).
- There is insufficient evidence to conclude whether boceprevir (Victrelis) or telaprevir (Incivik) is superior to the other, due to the lack of direct comparative trials.
- Telaprevir (Incivik) offers patient convenience due to its shorter treatment course than boceprevir (Victrelis) (12 weeks vs. 44 weeks), but this has not resulted in higher SVR rates.
- There is insufficient evidence to prefer one pegIFN-alfa-2 product (Pegasys vs. PEG-Intron) over the other, but there do not appear to be clinically relevant differences in efficacy.
- Interferon-alphacon-1 (Infergen) has poor efficacy and is not the standard of care for treatment of Chronic Hepatitis C. It no longer holds a niche in the treatment of prior null responders.
- Ribavirin is ineffective as monotherapy. With present regimens, it is critical for relapse prevention.
- Response-guided therapy maintains high levels of efficacy while shortening drug exposure time in clinically-appropriate patient populations.

Clinical Conclusions – continued

- Compared with dual therapy with PEG-interferon and ribavirin, boceprevir triple therapy increases the risk for anemia, and telaprevir triple therapy increases the risk for anemia and rash.
  - EPO allowed in boceprevir trials, but not usually with telaprevir trials
  - Clinically, ribavirin dose adjustment is used to manage anemia
- With boceprevir, unique AEs include dysgeusia, neutropenia & psychiatric events, compared to hemorrhoids, and anal burning/itching with telaprevir.
- Well known adverse events of ribavirin (>40%) with combination therapy are fatigue/asthenia, pyrexia, myalgia, and headache. Also pregnancy category X.
  - Interferon-alphacon-1 (Infergen) may reasonably be excluded from the formulary on clinical grounds; Ribapak, has no clinically compelling reason to be retained on the formulary.
  - Interferon-alfa-2b (Intron A) should be retained on the uniform formulary due to its non-Hepatitis C indications.

Final Decision: Hepatitis C Agents

- Extended Core Formulary (ECF):
  - Telaprevir (Incivik)
  - Peg-Interferon alfa-2a (Pegasys)
  - Ribavirin 200 mg capsules
- UF (all the ECF drugs plus the following):
  - Boceprevir (Victrelis)
  - Interferon alfa-2b (PEG Intron), Interferon alfa-2b (Intron A)
  - Ribavirin tablets (excludes Ribapak)
- NF:
  - Interferon-alphacon-1 (Infergen)
  - Ribapak formulation
- Implementation April 17, 2013

ECF includes meds in therapeutic classes for more specialized scopes of practice than those on the BCF. MTFs may choose whether or not to include an ECF therapeutic class on formulary, based on the clinical needs of its patients. However, if an MTF chooses to have an ECF therapeutic class on formulary it must have all ECF medications in that class on formulary.

Hepatitis C Drugs
Final Decision

ECF Medications	UF Medications	NF Medications	Comments
▪ telaprevir (Incivek) ▪ PEG-interferon alfa-2a (Pegasys) ▪ ribavirin 200 mg capsules (generics); excludes Ribapak formulation	▪ boceprevir (Victrelis) ▪ interferon alfa-2b (Intron A) ▪ PEG-interferon alfa-2b (PEG-Intron) ▪ ribavirin (Copegus, Rebetol, Ribasphere)	▪ interferon alfacon-1 (Infergen) ▪ ribavirin Ribapak formulation	▪ PA recommended for boceprevir and telaprevir ▪ QLs ▪ boceprevir & telaprevir: 28-day supply at all 3 POS; no multiple fills for multiple co-pays ▪ interferon products and ribavirin: 90-day supply in MTFs and Mail Order; 30-day supply at retail

New Drugs in Previously Reviewed Classes

Oxycodone IR (Oxecta)

Clinical Conclusion

- Oxecta is one of several abuse-deterrent opioids now on the market; 1st tamper resistant (not tamper-proof) IR oxycodone
- Uses Aversion technology (pharmaceutical excipients) to discourage abuse (IV and intranasal admin)
  - Polyethylene oxide: gel forming agent
  - Sodium lauryl sulfate: nasal tissue irritant
  - Can still abuse via oral route of administration
- FDA views these products as introducing "limits or impediments to abuse, as opposed to the elimination of abuse"
- Abuse liability study showed that despite higher incidence of nasal AEs, study subjects still reported liking Oxecta
- There are several abuse-deterrent formulations of opioids in the pipeline. Standardized and validated measures are needed in order to adequately evaluate these drugs
- Oxecta has no compelling clinical advantages conferred over other agents included on the UF

Oxecta Decision

- Designated as Non-Formulary
- Implementation April 17, 2013

Utilization Management

Utilization Management

- Generics to Lexapro and Protonix no longer NF
- Prior Authorizations updated for
  - Phosphodiesterase-5 Inhibitors
    - Post-prostatectomy: surgery must have been within 1 year of starting PDE-5; usage limited to one year
  - Testosterone Replacement Therapy
    - Use in women limited to 6 months
  - Injectable Gonadotropins (Fertility Agents)
    - New policy allows drugs in conjunction with IVF for severely ill/injured AD service members; signed authorization from TMA required with the Rx
  - Adalimumab (Humira) – ulcerative colitis added to PA criteria
  - Prostate cancer drugs: enzalutamide (Xtandi) & abiratone (Zytiga) – PA required; FDA indications (use of prior docetaxil-containing regimens)

Utilization Management – Quantity Limits

Drug	Quantity Limits
ipratropium/albuterol oral inhaler (Combivent Respimat)	• Mail Order and MTF: 5 inhalers/90 days • Retail: 2 inhalers/30 days
azelastine/fluticasone propionate nasal inhaler (Dymista)	• Mail Order and MTF: 3 inhalers/90 days • Retail: 1 inhalers/30 days
adalimumab (Humira)	Ulcerative Colitis • Initiation of therapy: Retail, Mail Order, and MTF: 6 syringes • Maximum quantity dispensed at any one time: Retail: 4-week supply (2 packs of 2 syringes) Mail order and MTF: 6-week supply (3 packs of 2 syringes)
enzalutamide (Xtandi)	• Mail Order and MTF: 45-day supply (180 capsules) • Retail: 30-day supply (120 capsules)
abiratone (Zytiga)	• Mail Order and MTF: 45-day supply (180 tablets) • Retail: 30-day supply (120 tablets)

Overview of February 2013 P&T Committee Meeting

February 2013
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Topical Pain (non-opioid)
    - Lidoderm patch, Voltaren gel, Pennsaid drops, Flector patch
  - COPD – Clinical evaluation
  - Oral Anticoagulants
- **New Drugs in Previously Reviewed Classes**
  - Zolpidem sublingual low-dose(Intermezzo)
- **Tretinoin Age limits**
- **Quantity Limits**
  - Aclidinium oral inhaler (Tudorza)
  - Beclomethasone nasal inhaler (Qnasal)
  - Posatinib (Iclusig)

Quick Look at May 2013 P&T Committee Meeting

May 2013
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - COPD Cost evaluation, and UF and BCF decisions
  - Gout Products
    - Allopurinol
    - Uloric
    - Colcrys
  - Smoking Cessation
    - Cost re-analysis due to publication of Final Smoking Cessation Rule
  - Topical Steroids – clinical evaluation

Other Issues

Other Issues

- Smoking Cessation
  - Final Rule Published February 27, 2013
  - https://www.federalregister.gov/articles/2013/02/27/2013-03417/tricare-smoking-cessation-program
  - More details coming soon from the PEC
- Warfarin contract
  - MTFs encouraged to comply with contracted product (Golden State)
- Next Choice (levonorgestrel 0.75 mg) BCF status
  - BCF product D/C'd; will address at May P&T meeting
- Zolpidem products – lower dosages for women
  - 5 mg for IR products (Ambien, Edluar, and Zolpimist)
  - 6.25 mg for ER products (Ambien CR)
  - FDA alert at http://www.fda.gov/drugs/drugsafety/ucm334033.htm

Miscellaneous items

- PEC website
  - Email questions to PECUF@amedd.army.mil
- PECUF@amedd.army.mil
  - For other questions, formulary clarification, etc
- Next webcast will be held on June 13th 2013 at 0900 and 1700 EST

Questions?

Webcast Evaluations

- Please assist us in improving the webcast presentations by completing an anonymous, 5-question survey
- Link: http://www.zoomerang.com/Survey/WEB22CTVSNWFRP
- Thank you!

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    - Clinical, formulary questions