Drug Utilization Review Board Meeting Minutes, Open Session January 13, 2010		
Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital / Cedar Crest Room Topeka, KS	**Members Present:** Michael Burke, M.D., Ph.D., Chair John Kollhoff, Pharm.D. Judy McDaniel Dowd, PA-C Brenda Schewe, M.D. Roger Unruh, D.O. Kevin Waite, Pharm.D. **KHPA Staff Present:** LeAnn Bell, Pharm.D. Aimee Grubb, Recorder Shelly Liby **HP Enterprise Services Staff Present:** Karen Kluczykowski. R.Ph. Deb Quintanilla, R.N. Lisa Todd, R.Ph. **HID Staff Present** Nicole Churchwell, Pharm.D.	**Representatives:** Jerry Clewell, Abbott Mike LaFond, Abbott Sarah White, Abbott Paul Konovodoff, Acorda Teresa Blair, Amgen Charles Dahm, Amgen Cyndee Davies, AstraZeneca Randy McGinley, Bayer Don Larsen, Forest Dana Evans, Genetech Patty Laster, Gennetech Dave Walters, J & J Susan Zalenski, J & J Todd Holdsworth, J & J Barbara Belcher, Merck Matt Stafford, Merck David Topham, NNI Phil King, Pfizer Wanda Stipek, Sanofi-Aventis Bruce Steinberg, Sanofi-Aventis Joe Summers, Takeda Tracey Gasperi, UCB Curt Griffith, UCB
TOPIC	**DISCUSSION**	**DECISION AND/OR ACTION**
I. Call to Order	Dr. Burke, Chair called the meeting to order at 10:05 a.m.	
II. Announcements	Dr. Bell asked the public to fill out the conflict of interest forms if they wanted to speak to the board. There is a limit of five minutes per drug.	
III. HID Outcomes Assessment	Outcomes assessments for the interventions performed by HID in June, 2009 were presented at the meeting. In May, 2009 the intervention topics selected were asthma, NSAID/COX II inhibitors, and narcotic utilization to complete state fiscal year (SFY) 2009. All three of these interventions were performed together due to the time frame. <u>Intervention Summary</u> **Intervention Mailing Date** June 23, 2009 **Pre-Intervention Period** February 2009-June 2009 **Post-Intervention Period** July 2009-October 2009 **Profiles Reviewed** 2,585	

Profiles Resulting in a Case	1,859
Letters Generated	2,419
Letters Mailed	1,688
Responses Received	657

Estimated Cost Savings

Number of Patients	1,239
Pre-Intervention Costs	$3,695,003.49
Post-Intervention Costs	$3,413,560.35
Difference	$281,443.14

*Pre & Post Intervention periods are 120 days with a null period of 14 days to account for mailing & receiving of letters.

Activity Report

Intervention Topic	**Asthma**	**Narcotic**	**NSAID/COX-II Inhibitors**	**Total**
Letters Generated	442	1,447	529	2,419
Letters Deleted in QA	161	456	111	728
Letters Mailed	281	991	416	1,688
Responses Received	92	412	153	657
Response Rate	32.7%	41.6%	36.8%	38.9%

Distribution of Letters by Problem Type

The potential drug therapy problems reviewed fall into five categories. The categories of drug therapy problems and percentage of letters in each category identified were as follows:

Drug-Disease Interactions 40%
Patients receiving a drug that may worsen or precipitate a medical condition.

Drug-Drug Interaction 31%
Patients receiving two or more drugs that, when taken together, may interact and produce unpredictable and undesirable effects.

Over-Utilization 18%
Patients taking medications in apparently excessive doses or for excessive lengths of time.

Under-Utilization 1%
Patients taking medications for the treatment of chronic conditions at levels below the normal minimum effective dose.

Clinical Appropriateness 11%
Therapeutic appropriateness is defined as patients who are NOT taking medications for the treatment of a disease in which the medication is current practice standard of care. Cost appropriateness and appropriate use of generics are also included in this category.

NSAID/COX-II Inhibitors Distribution of Letters

Drug Therapy Problem	# of Letters Mailed	% of Total Letters
Drug-Drug Interaction	192	46.2%
Clinical Appropriateness	29	7.0%
Drug-Disease Interaction	197	47.4%
Total	416	

NSAID/COX-II Inhibitors Prescriber Responses

Letter Responses	Responses Received	% of Responses
- Doctor has not modified drug therapy because benefits of drug outweigh the risks	28	18.3%
- Doctor was unaware of what others were prescribing	3	2.0%
- Patient is no longer under my care	16	10.5%
- Doctor has reviewed the information and will continue without change	35	22.9%
- Doctor has reviewed the information and will modify drug therapy	11	7.2%
- Doctor will not discuss drug therapy conflict with patient	16	10.5%
- Doctor has tried to modify therapy, however the patient refuses to change	5	3.3%
- Patient is under my care but has not seen me recently	7	4.6%
- Patient was never under my care	8	5.2%
- Patient has an appointment to discuss drug therapy	9	5.9%
- Doctor did not write the medication attributed to them	7	4.6%

- Doctor has tried to modify therapy, however symptoms reoccurred	1	0.7%
- Doctor saw patient only once while in ER or covering on-call	7	4.6%

Asthma Distribution of Letters

Drug Therapy Problem	# of Letters Mailed	% of Total Letters
Drug-Disease Interaction	23	8.2%
Drug-Drug Interaction	119	42.2%
Over-Utilization	25	8.9%
Under-Utilization	20	7.1%
Clinical Appropriateness	94	33.5%
Total	281	

Asthma Prescriber Responses

Letter Responses	Responses Received	% of Responses
- Doctor has not modified drug therapy because benefits of drug outweigh the risks	5	5.4%
- Doctor was unaware of what others were prescribing	3	3.3%
- Patient is no longer under my care	4	4.3%
- Doctor has reviewed the information and will continue without change	18	19.6%
- Doctor has reviewed the information and will modify drug therapy	12	13%
- Doctor will not discuss drug therapy conflict with patient	15	16.3%
- Doctor has tried to modify therapy, however the patient refuses to change	4	4.3%
- Patient is under my care but has not seen me recently	5	5.4%
- Patient is recently deceased	1	1.1%
- Patient was never under my care	2	2.2%
- Patient has an appointment to discuss drug therapy	13	14.1%
- Doctor did not write the medication attributed to them	2	2.2%
- Doctor has tried to modify therapy, however	2	2.2%

symptoms reoccurred		
- Doctor saw patient only once while in ER or covering on-call	6	6.5%

Narcotic Distribution of Letters

Drug Therapy Problem	# of Letters Mailed	% of Total Letters
Drug-Disease Interaction	450	45.4%
Drug-Drug Interaction	212	21.4%
Over-Utilization	274	27.7%
Clinical Appropriateness	55	5.6%
Total	991	

Narcotic Prescriber Responses

Letter Responses	Responses Received	% of Responses
- Doctor has not modified drug therapy because benefits of drug outweigh the risks	32	7.8%
- Doctor was unaware of what others were prescribing	15	3.6%
- Patient is no longer under my care	35	8.5%
- Doctor has reviewed the information and will continue without change	121	29.4%
- Doctor has reviewed the information and will modify drug therapy	28	6.8%
- Doctor will not discuss drug therapy conflict with patient	22	5.3%
- Doctor has tried to modify therapy, however the patient refuses to change	14	3.4%
- Patient is under my care but has not seen me recently	25	6.1%
- Patient is recently deceased	3	0.7%
- Patient was never under my care	10	2.4%
- Patient has an appointment to discuss drug therapy	42	10.2%
- Doctor did not write the medication attributed to them	12	2.9%
- Doctor has tried to modify therapy, however symptoms reoccurred	28	6.8%
- Doctor saw patient only once while in ER or	25	6.1%

	covering on-call Dr. Burke asked if the prescriber responses are standard. Dr. Churchwell said there is a list of responses to choose from, but they also had the opportunity, if the prescriber wanted, to fill in any additional comments. Dr. Burke asked if there were any interesting responses. Dr. Churchwell said some of the prescribers found the letters to be helpful, especially if they didn't know what other prescribers were writing. There was also a prescriber that said he felt the letter was another useful tool to show uncooperative patients to try to convince them to change their therapy. Dr. Schewe asked about the response rate. Dr. Churchwell said typically 30% is a good response rate. Dr. Waite said the asthma intervention seemed more effective than the others.	
IV. Old Business A. Review and Approval of 10/21/09 Meeting Minutes	No changes made.	Dr. Unruh moved to approve the minutes. Dr. Waite seconded and it carried with a unanimous vote.
B. Short-Acting Opioids	**CRITERIA FOR High Dose Override** **MANUAL GUIDELINES:** The following drugs at morphine equivalents greater than 200 mg per day require override for high dose: Hydromorphone (Dilaudid ®) Morphine sulfate (MSIR®, Roxanol®) Oxymorphone (Opana®) Oxycodone (Roxicodone®) Oxycodone/APAP (Percocet®) ~~Methadone (Methadose®)~~ Hydrocodone/APAP (Vicodin, Lortab®) CRITERIA: Must meet one of the following: • Patient is terminally ill. • Diagnosis of cancer. • Concurrent therapy with a long-acting opioid. o If beneficiary had a documented inability to tolerate long-acting opioids, concurrent therapy is not required • Inadequate management of pain with short-acting opioids at total daily dose equivalent to or less than of 200 mg morphine ~~AND consult with pain management specialist~~. **Length of Prior Authorization: 1 year**	Dr. Schewe moved to accept the PA criteria eliminating bullet four and changing the length of PA to three months. Ms. Dowd seconded and it carried with a unanimous vote

	This topic was tabled during the July DUR Board meeting to allow for utilization data to be gathered. Currently, there is not a daily limit for short-acting opioids. Claims for large quantities of most combination products (e.g. Lortab®, Percocet®) will exceed the high-dose limit for the other component (e.g. acetaminophen), but the opioid component itself does not. Hydromorphone (Dilaudid®) does have a limit on the opioid component. Recently released guidelines from the American Pain Society suggest greater than 200mg of morphine equivalents require closer monitoring. Dr. Burke said the data has been reviewed from the American Academy of Pain Opioid Guidelines that appeared in the Journal of Pain in 2009. Consensus opinion is when you get above 200mg per day of morphine equivalence the patients need to be monitored more closely. No public comment. Dr. Schewe was concerned with the length of the PA and bullet 4. Dr. Waite said the fourth bullet obviates the need for a physician to have a patient meet any of the other three criteria. It is not effective pain management. Dr. Burke asked how bullet three, combined with the sub-bullet, differs from bullet four. Dr. Schewe suggested eliminating the fourth bullet. Dr. Burke referred to the position in the guidelines that stated long-acting opioids may not be appropriate for all patients. Dr. Kollhoff said long-acting opioids are expensive compared to the short-acting. Dr. Schewe has concerns with those patients who require medication to cope with life, not cancer patients. Dr. Burke asked what the reasonable time frame would be. Dr. Schewe said three months. Dr. Kollhoff said there is a push in the legislature to create a controlled substances tracking program. Dr. Bell said it is the Prescription Drug Monitoring Program. Grant funding has recently been secured so it will probably be a year or two before the program can be implemented. Dr. Burke asked if three months is burdensome. Dr. Bell asked if the length of PA should be left at one year for terminal patients. Dr. Burke asked if it can be AutoPA. Dr. Bell said since it will be a Super PA it can't go through AutoPA. Dr. Burke suggested we put the length at one year for cancer patients and three months for all other patients. Dr. Schewe said there are all kinds of cancer. Dr. Waite said the board can revisit this again in three months. Dr. Bell suggested requesting some sort of documentation, i.e. a letter from an oncologist or set the length at three months for everyone. Dr. Burke would prefer to go with three months for everyone.	
V. New Business A. Statins	Dr. Bell said this is an informational notification for the DUR Board about PDL Committee activity. The HMG CoA Reductase Inhibitors are currently on the Preferred Drug List.	

	Recently Livalo® (pitavastatin), a new agent in this class, was reviewed by the PDL Committee and approved for addition to the PDL. The DUR Board has previously reviewed and approved a standard Statin PDL form, so this is an information-only update on the addition of an agent to the class. No public comment. Dr. Burke said that the PDL Committee found that pitavastatin was clinically equivalent to the other statins that are currently available. Dr. Bell will add it to the current PDL.	
B. Proton Pump Inhibitors	Recently, a drug interaction between the Proton Pump Inhibitors (PPIs) and Plavix® (clopidogrel) has been reported. The FDA has issued an alert regarding the interaction between clopidogrel and omeprazole (Prilosec® & Prilosec OTC®). Dr. Burke said the PDL Committee did not act on this. No public comment. Dr. Burke spoke with the pharmacy at Via Christi Medical Center. Their position is that they are aware of this potential interaction. They are alerting physicians when occasion arises. The data is still in development phase and they have no set policy. Dr. Schewe said there is no auto substitution. The PPIs are inhibiting the metabolism of clopidogrel to the active agent therefore reducing its anticoagulant effects. Information was provided that suggested all the PPIs have the potential to inhibit 2C19, to different degrees, but not significant. There is more recent data that suggests that pantoprazole is less likely to inhibit 2C19. Dr. Burke said options would be to keep the PA as is, but provide the opportunity to accept prescribers concern about possible drug interactions as criteria under medical intolerance to allow them to use non-preferred agents. Wanda Stipek, Sanofi-Aventis, said the latest label change to Plavix®, around this issue, has recommended clinicians avoid omeprazole and esomeprazole. The direction from the FDA and the makers of Plavix® is to use other PPIs. There are options other than just Protonix® (pantoprazole) which would include rabeprazole and lansoprazole. The majority of the evidence would suggest that rabeprazole, lansoprazole, and pantoprazole would be prudent choices as well. Dr. Burke said when you look at the K_I values lansoprazole appears to bind with equal potency to 2C19 as omeprazole. Ms. Stipek said it has been difficult to translate the lab bench work type research into clinical recommendations. What was seen with the lansoprazole study has been repeated in other types of ex vivo data. The data for anti-platelet activity was not as large of an effect as seen with omeprazole. The difficulty is determining whether these are clinically relevant. The package insert was updated in May, 2009 and then again in October, 2009. Dr. Burke asked if there is any comment in the	Dr. Schewe moved that clinicians, who seek an alternative for patients taking Plavix®, receive education about alternatives and have the option of having a non-preferred agent for that patient. Dr. Kollhoff seconded and it carried with a unanimous vote.

	package insert about using 2 antagonists. Ms. Stipek said H2 blockers are considered to be safe alternatives with the exception of tagamet or cimetidine because they are also 2C19 inhibitors. Antacids also may be a safe alternative. Dr. Waite asked Ms. Stipek if she has any recommendations for physicians, in this situation, to consider the Verifynow test for anti-platelet activity. Ms. Stipek said there is emerging evidence in the literature for the use of various types of platelet measurements. At this time none of those have been established as a well referenced therapeutic window with set points for lower and upper thresholds and until those numbers can be replicated and linked to clinical outcome, i.e. treatment failure or excess bleeding, their use in clinical practice is still considered exploratory. Sanofi-Aventis does not have any recommendations about the use of those agents. Dr. Waite said they still have other alternatives available on the PDL. A physician has viable alternatives to choose for their patient, that shouldn't adversely affect their care, so he didn't think the board needed to do anything. Dr. Burke said if a prescriber wants pantoprazole for a patient on Plavix® it would be accepted under medical intolerance. Dr. Bell asked if we would educate them. Dr. Burke said we can because it is still uncertain, but we shouldn't withhold. Dr. Kollhoff asked if we could automatically allow Protonix® when Plavix® is used. Dr. Burke said there is no documentation that suggests that this should be changed.	
C. Gliptins	The DDP-4 inhibitors (gliptins) were reviewed and approved for addition to the Preferred Drug List by the PDL committee in December 2009. There are two agents in this class: sitagliptin (Januvia®) and saxagliptin (Onlglyza®). Matt Stafford, Merck, said there are four key elements to think about when treating diabetic patients. The latest survey data shows that in this country we still have about 40-50% of patients not achieving their A1C goals. Additionally, expert panels continue to support more aggressive early treatment with multiple drug regimens along with therapeutic lifestyle changes. There is a growing body of evidence that placing restrictions on diabetic medications leads to lessening of patient outcomes, so reducing barriers or restrictions can improve patient outcomes. That is supported by published literature that has been peer reviewed. Finally, regarding in-class competitors, history has shown that within categories like statins, COX II inhibitors, and oral anti-diabetics, an in-class comparison of the two being similar are oftentimes more dissimilar than similar. Mr. Stafford asked the board to consider, when developing the criteria, if there is a criteria for use for a non-PDL product that it simply require the use of any oral anti-diabetic PDL drug; not just the gliptin category, but any PDL drug because of the complexities of treating diabetics, the need for multiple medications, the in class issues that can arise within same class drugs that are dissimilar. Dr. Burke said the PDL did find that these agents are clinically equivalent. We don't want	Dr. Schewe moved to approve the PA form for gliptins with the preferred and non-preferred agents chosen based on pricing data. Dr. Kollhoff seconded and it carried with a unanimous vote.

	to be restrictive to practitioners or patients, so if the practitioner feels that the patient can't tolerate the preferred agent, it isn't efficacious, or there isn't an appropriate formulation with regard to age or root of delivery the practitioner can check the box and can get a non-preferred agent for their patient.	
D. Long-Acting Insulins	The long-acting insulins were reviewed and approved for the addition to the Preferred Drug List by the PDL committee in December 2009. There are two agents in this class: insulin detemir (Levemir®) and insulin glargine (Lantus®). Dr. Burke received a letter from a provider stating that both agents should be available. Once again the reminder is that whether it is preferred on non-preferred, all agents are available. No public comment.	Ms. Dowd moved to accept the PA criteria for long-acting insulins. Dr. Waite seconded and it carried with a unanimous vote.
E. Biologics	Dr. Bell said the biologics were reviewed by the PDL Committee and approved for inclusion on the PDL in December 2009. There are 11 agents in the class; six have multiple indications, five have only one FDA labeled indication. All indications except for ulcerative colitis have multiple agents approved for use in that disease state. The PDL Committee approved designation of preferred agent(s) for each indication. Each indication will form its own PDL class. (i.e. if the request is for Ankylosing spondylitis, Cimzia would not be part of that PDL class because it is not indicated for that disease state). There is a caveat in adult Rheumatoid Arthritis (RA). Rituxan®, Simponi®, and Remicade® are not equivalent to other agents in that class because they must be used in conjunction with Methotrexate/DMARD therapy. For each indication there are some drugs that can be used first line without having had to fail Methotrexate/DMARD first. There are others that can only be used second line after failure of Methotrexate/DMARD. If there is a first line agent that is designated as non-preferred and there is a second line agent designated as a preferred, in those instances the prescriber can say they don't want to use Methotrexate/DMARD and that will be treated as if they have used that agent, therefore they will be able to get the other one that has been approved as first line. Dr. Burke said the issue is to approve organizing the drugs by diagnosis rather than class. At the PDL meeting there was a lengthy discussion of biologics. There are many subtle differences in the immune modulators in terms of binding sites and where they are targeting their effect on immune function. We are on the cutting edge of medicine with these agents. In time sub-classes may begin to be developed. **CRITERIA FOR Biologics for Treatment of Ankylosing Spondylitis** (as recommended by the Drug Utilization Review Committee) 1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug.	Dr. Kollhoff moved to organize biologics/immune modulators by disease state. Dr. Unruh seconded and it carried with a unanimous vote. Dr. Kollhoff moved to approve the standard PA criteria. Ms. Dowd seconded and it carried with a unanimous vote.

	OR 3. Absence of appropriate formulation or indication of the drug. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** **CRITERIA FOR Biologics for Treatment of Crohn's Disease** (as recommended by the Drug Utilization Review Committee) 1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug. OR 3. Absence of appropriate formulation or indication of the drug. OR 4. If preferred agent requires initial use of DMARD/MTX prior to use of preferred agent, provider statement that DMARD/MTX is not appropriate for patient will be treated as a trial of the preferred agent. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** **CRITERIA FOR Biologics for Treatment of Juvenile Idiopathic Arthritis** (as recommended by the Drug Utilization Review Committee) 1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug. OR 3. Absence of appropriate formulation or indication of the drug. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** **CRITERIA FOR Biologics for Treatment of Plaque Psoriasis** (as recommended by the Drug Utilization Review Committee) 1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug.	

	OR 3. Absence of appropriate formulation or indication of the drug. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** **CRITERIA FOR Biologics for Treatment of Psoriatic Arthritis** (as recommended by the Drug Utilization Review Committee) 1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug. OR 3. Absence of appropriate formulation or indication of the drug. OR 4 If preferred agent requires initial use of DMARD/MTX prior to use of preferred agent, provider statement that DMARD/MTX is not appropriate for patient will be treated as a trial of the preferred agent. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** **CRITERIA FOR Biologics for Treatment of Rheumatoid Arthritis** (as recommended by the Drug Utilization Review Committee) 1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug. OR 3. Absence of appropriate formulation or indication of the drug. OR 4. If preferred agent requires initial use of DMARD/MTX prior to use of preferred agent, provider statement that DMARD/MTX is not appropriate for patient will be treated as a trial of the preferred agent. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** **CRITERIA FOR Biologics for Treatment of Ulcerative Colitis** (as recommended by the Drug Utilization Review Committee)	

	1. Documentation including clinical symptoms from prescribing physician of medical intolerance to preferred drug OR 2. Notation of inadequate response to preferred drug. OR 3. Absence of appropriate formulation or indication of the drug. **Prior Authorization may be approved for up to one year time period. If there has been no change in the Preferred Drug List (what would indicate further review), renewals may be approved for an additional one year period.** Charles Dahm, Amgen, said Enbrel® is distinct in that it is a soluble TNF receptor fused to a fragment of the Fc portion of human IgG1. There are some differences in labeling with respect to pediatric dosing and the age groups in which those molecules can be used. Enbrel® is approved for use in children with Juvenile Idiopathic Arthritis (JIA) down to two years of age. Phil King, Pfizer, asked Dr. Bell if the attempt would be to do this clinically transparently. Dr. Bell said we envision it happening as it does now, with a clinical prior authorization and based on what indication the prescriber is requesting we will then look at whether they are asking for a preferred or non-preferred; if it is a non-preferred they will have to fill out the PDL non-preferred request. Dr. Burke clarified that the prescriber has to provide the diagnosis codes. Mr. Dahm pointed out that Enbrel® is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel® can be used in combination with Methotrexate in patients who do not respond adequately to Methotrexate alone. Dr. Bell said she would make sure the criteria are correct. Dr. Churchwell said the criteria needs to be approved as well.	
F. Cimzia®	Prior authorization criteria for Cimzia® was initially approved in November 2008. An additional indication for the treatment of Rheumatoid Arthritis has been approved by the FDA. **CRITERIA FOR Prior Authorization** Anti-Tumor Necrosis Factor - alpha **MANUAL GUIDELINES:** The following drugs require prior authorization: Certolizumab pegol (Cimzia®) **Criteria for Crohn's Disease** (Must meet all of the following): • Diagnosis of moderate to severe, active Crohn's Disease • Documentation of inadequate response to conventional therapies.	Dr. Waite moved to accept the changes to the PA criteria for Cimzia®. Dr. Schewe seconded and it carried with a unanimous vote.

	Conventional therapy for Crohn's Disease would include the following drugs: 5-ASA (Mesalamine and Rowasa), Sulfasalazine, Corticosteroids (prednisone, etc.), Budesonide (Entocort EC). • Prescribed by a gastroenterologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Must be 18 years of age or older **Criteria for Rheumatoid Arthritis** (Must meet all of the following): • Diagnosis of moderately to severely active rheumatoid arthritis • Prescribed by a rheumatologist • Patient must be 18 years of age or older • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA **NOTE:** This drug carries a Black Box Warning: Risk of serious infections. Cimzia should not be used in combination with biological DMARDs or other tumor necrosis factor (TNF) blocker therapy. **Prior Authorization will be approved for six (6) months.** No public comment.	
G. Stelara®	Stelara® is a newly approved medication for the treatment of Plaque psoriasis. Currently, the other agents in this class require prior authorization. We propose prior authorization criteria for this drug to maintain consistency in the class. **CRITERIA FOR Prior Authorization** Stelara® (ustekinumab) **MANUAL GUIDELINES:** The following drugs requires prior authorization: Ustekinumab (Stelara®) **Criteria for plaque psoriasis:** (must meet all of the following) • Patient must be 18 years of age or older • Patient must have a diagnosis of plaque psoriasis • Patient must be a candidate for systemic therapy or phototherapy • Must be prescribed by a Dermatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA **NOTE:** Stelara® should not be in combination with other immunosuppressive agents or phototherapy. Patients should not receive live vaccinations while being treated with Stelara. **Prior Authorization will be approved for six (6) months.** No public comment. Dr. Waite asked about patient's being candidates for phototherapy, but the note said Stelara® should not be used in combination with phototherapy. Ms. Dowd said it means they don't respond to topical treatment. Dr. Burke asked if Stelara® can be used with	Dr. Unruh moved to accept the PA criteria for Stelara®. Dr. Schewe seconded and it carried with a unanimous vote.

	topical treatments. Ms. Dowd said yes, but if patients comes in with early onset of psoriasis some could ask to go right to Stelara® instead of receiving the conservative topical treatment, this prevents that from happening. Dr. Burke clarified that it can be used in conjunction with topical therapy, but not phototherapy. Dr. Kollhoff said systemic therapy is unclear. Dr. Schewe said the patient must be a candidate for systemic therapy not meaning versus topical. Dr. Kollhoff asked if we are trying to get the patients to try topical first. Dr. Schewe said no, if they are severe enough to warrant systemic therapy then they are a candidate for Stelara®.	
H. Rituxan®	Rituxan® is indicated for the treatment of rheumatoid arthritis. Currently, the other agents used to treat rheumatoid arthritis require prior authorization. We propose prior authorization criteria for this drug to maintain consistency in the class. The criteria for Non-Hodgkin's Lymphoma (NHL) is lenient so that it is accessible to those patients. **CRITERIA FOR PRIOR AUTHORIZATION** Rituxan® (rituximab) **MANUAL GUIDELINES:** The following drug requires prior authorization: Rituximab (Rituxan®) **Criteria for Non-Hodgkin's Lymphoma (NHL):** (must meet all of the following) • Patient must be 18 years of age or older. • Patient must have a diagnosis of Non-Hodgkin's Lymphoma **Criteria for Rheumatoid Arthritis:** (must meet all of the following) • Patient must be 18 years of age or older. • Patient must have a diagnosis of moderate to severe, active Rheumatoid Arthritis. • Must be prescribed by a Rheumatologist. • Must be given in combination with methotrexate. • Must have documentation of inadequate response to one or more TNF antagonist therapies. • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA. **Warnings:** This drug carries a Black Box Warning. Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, and progressive multifocal leukoencephalopathy. **Prior Authorization will be approved for six (6) months.** Dr. Schewe asked if it should be prescribed by an oncologist. Dr. Churchwell said we can add that. Dr. Burke asked when Rituxan® was made available. Dr. Churchwell said it has been available for awhile, but we haven't put it on PA due to NHL. Dana Evans, Genetech, said it was approved for NHL in 1997 and approved for RA in 2006. New label information was added in October, 2009. Four clinical trials, looking at a variety of different things including documentation of retreatment, were submitted to the FDA at the end of 2008. The initial clinical trials only one treatment of two infusions was in the	Ms. Dowd moved to accept the PA criteria for Rituxan® with changes discussed. Dr. Kollhoff seconded and it carried with a unanimous vote.

	clinical data. On the retreatment data the standard protocol was retreatment at 24 weeks. The label was updated to indicate that treatment is recommended for Rituxan® every 24 weeks or as indicated by clinical evaluation but not sooner than 16 weeks. Dr. Evans had a concern about the length of the PA since retreatment should occur every 24 weeks. Dr. Burke said the six month approval is standard for this class. Ms. Dowd asked Dr. Evans about his concern about the time frame. Dr. Evans said the recommended treatment interval is 24 weeks from the date of the first infusion; that is two weeks shorter than six months. Physicians could do retreatment as early at 16 weeks which would be about four months. His concern is will the physicians try to squeeze in the second dose under the original authorization, so four infusions. Or doctors will need to reauthorize if they go longer than six months. Dr. Burke asked what the dosing recommendation is for NHL. Dr. Evans said it's generally 375mg/kg, every week for four-eight weeks in duration for active treatment. For maintenance it's every week for four weeks and it is repeated every six months for two years. Dr. Burke asked Ms. Dowd if it would be a burden to reauthorize. Ms. Dowd said no. Dr. Kollhoff said he thinks it is prudent to leave it at six months. Dr. Burke asked about the concern Dr. Schewe raised. Dr. Bell said we can add "must be prescribed by an oncologist" to the NHL criteria. Dr. Kollhoff pointed out in the warnings that the second sentence is not complete; should add "may occur".	
I. Tysabri®	Tysabri® received FDA approval for treatment of Crohn's disease in 2008. Currently, other agents used for the treatment of Crohn's Disease require a prior authorization. We propose prior authorization criteria for this drug to maintain consistency in the class. **CRITERIA FOR PRIOR AUTHORIZATION** Tysabri® (natalizumab) **MANUAL GUIDELINES**: The following drugs requires prior authorization: Natalizumab (Tysabri®) **Criteria for Crohn's Disease (CD):** (must meet all of the following) • Patient must be 18 years of age or older. • Patient, Prescriber and Infusion Center must be registered with the CD Touch Program. • Patient must have a diagnosis of moderate to severe, active Crohn's Disease with evidence of inflammation. • Must have documentation of inadequate response to, or inability to tolerate, conventional Crohn's Disease therapies and TNF inhibitors. **Criteria for Crohn's Disease (CD) Renewal:** • Documentation of therapeutic benefit is required for renewal after initial three	Dr. Waite moved to accept the PA criteria for Tysabri® with changes discussed. Dr. Schewe seconded and it carried with a unanimous vote.

	months of therapy. • Documentation of discontinue of chronic steroid use (if applicable) is required for renewal after initial 6 months of therapy. **Criteria for Multiple Sclerosis (MS):** (must meet all of the following) • Patient must be 18 years of age or older. • Patient, Prescriber and Infusion Center must be registered with the MS Touch Program. • Patient must have a diagnosis of multiple sclerosis. • Must have documentation of inadequate response to, or unable to tolerate, an alternate multiple sclerosis therapy. **NOTE:** This drug carries a Black Box Warning: Progressive multifocal leukoencephalopathy (PML). A baseline brain MRI may be helpful to distinguish pre-existent lesions from newly developed lesions caused by PML. **All Prior Authorizations for Multiple Sclerosis will be approved for six (6) months. First two Prior Authorizations for Crohn's Disease will be approved for three (3) months; all subsequent renewals will be approved for six (6) months.** Dr. Schewe asked if we should add who is prescribing for Crohn's Disease (CD) and Multiple Sclerosis (MS). Dr. Burke said a nice thing is that the manufacturer has a safety program and the patient and prescriber has to be enrolled. Dr. Schewe said the prescribing should come from a specialist. She feels that we should add a bullet under CD that says must be prescribed initially by a Gastroenterologist and a bullet under MS that says must be prescribed initially by a Neurologist. Dr. Waite said that is a good idea. Ms. Dowd said under CD renewal should add a bullet that says must meet criteria above. No public comment.	
VI. Adjourn	The meeting was adjourned at 12:01 p.m. with no final comments.	Dr. Schewe moved to adjourn the meeting. Dr. Unruh seconded and it carried with a unanimous vote.