

November 20, 2014 MAC  
Binder Section 13 – Miscellaneous Part B  
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CABINET FOR HEALTH AND FAMILY SERVICES  
DEPARTMENT FOR MEDICAID SERVICES

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Audrey Tayse Haynes  
Secretary

Lawrence Kissner  
Commissioner

MEMORANDUM

TO: Lawrence Kissner, Commissioner

*Copy for staff mtg  
+ MAC*

FROM: Patricia Biggs, RN *RB*  
Director, Division of Program Quality & Outcomes

DATE: November 17, 2014

SUBJECT: Request from the MAC concerning a common Prior Authorization process

At the request of the MAC, the Department for Medicaid Services has formed a workgroup to explore a common Prior Authorization (PA) process to be utilized by the Managed Care Organizations (MCO). The task is to determine the feasibility of a common form or process to be used in obtaining a prior authorization.

The workgroup is composed of representatives of each MCO plus representatives from the Department for Medicaid Services. Members are: Dr. Stephen Hoagland, Medicaid Director Passport; Dr. Fred Tolin, Medical Director Coventry; Dr. Howard Shaps, Medical Director WellCare; Dr. Vaughn Payne, Medical Director, Humana; Jeff Sutherland, Manager II Healthcare Management Services Behavioral Health Anthem; Matthew Fitzner, Director of Healthcare Management Services Anthem; Patricia Biggs, Director and Cindy Arflack, Assistant Director, DMS Program Quality & Outcomes.

Research has been conducted to assess how other states have tackled this issue. Ohio developed a common form for an authorization request. A copy of the form is included for review. Ohio also developed a grid that details PA requirements for category of service across their Managed Care plans. It is not detailed as to specific codes but rather the type of service being authorized.

Nevada shared that though they only have two (2) Medicaid MCOs, there were differences with certain prior authorization requirements. A spreadsheet was developed with the codes in question. PA requirements were listed for each of those codes and they then tried to align the requirements. Nevada has fax and online portal submissions for the prior authorization process. They did not develop a common form for submission.

At the workgroup meeting on October 29, 2014, the positive and negatives aspects of the common PA form/process was discussed. A summary of the discussion points is below.

**PRO:**

- Less administrative burden for providers.
- Tracking of services authorized may be easier when a member moves from one MCO to another.
- Improved documentation and/or completion of the form if a standard form is utilized by all MCOs.
- No reason for use of a provider developed "homegrown" form for submission.

**CON:**

- Specific items on the form cue the area that is to review the service request as well as the form is designed to reflect the information needed for the specific request.
- Differences in criteria would impact the clinical criteria and documentation required.
- One form expected to cover all documentation needed for multiple services would be lengthy.
- A common formulary for medications would have a dramatic impact on pricing/costs due to the different PBM contracting that exists within the industry.
- Corporate forms are often utilized and the MCO systems designed to use the specific form.
- Changes to the MCO established systems to accommodate a single form will be very costly and time consuming.
- Increased likelihood of HIPAA breach since forms would no longer be visually discernable from one MCO to the next.
- The unique form each MCO utilizes contains specific MCO contact information.
- Multiple fax numbers on one form will increase the chance of error or even lost requests.
- Movement to a state specific form would create opportunity for errors and delays to members and providers.

**Workgroup suggestions:**

- The workgroup would like specific recommendations from the MAC as to the changes requested in the PA process.
- Each MCO would be willing to provide training for provider staff in properly completing a PA request form.
- Encourage the use of on-line prior authorization request submission.
- Continue the workgroup discussions until a satisfactory outcome results.

**Take Away:**

- Each MCO is to provide the Department the volume of requests received by each source-phone, fax and on-line portal submissions.
- Each MCO is to provide a list of the codes that require prior authorization along with any special requirement or limitation for the service.



## PRIOR AUTHORIZATION FORM

\* For URGENT requests please contact MCP by phone\*

Today's Date:

MCP Name:

<b>1.</b>	<b>Member ID</b>	<b>DOB</b>	
	<b>Last Name</b>	<b>First Name</b>	
	<b>Member Phone Number (      )</b>		
<b>2.</b>	<b>Is there another Insurance Carrier for this service?</b>		
	<input type="checkbox"/> YES <input type="checkbox"/> NO		
	If yes, name of company		Policy Number:
<b>3.</b>	<b>Referral Service Type Requested</b>		
	Please refer to the Plan's Prior Authorization List for those services that require prior authorization		
	Ambulatory Surgery	<input type="checkbox"/>	Out of Network Provider <input type="checkbox"/>
	Cosmetic/Plastic Procedure	<input type="checkbox"/>	Diagnostic Testing <input type="checkbox"/>
	Elective/Scheduled Admission	<input type="checkbox"/>	Office Procedure <input type="checkbox"/>
	DME/Home Infusion	<input type="checkbox"/>	OB Services <input type="checkbox"/>
	Pain Management	<input type="checkbox"/>	Specialty Referral <input type="checkbox"/>
	Outpatient PT/OT/ST	<input type="checkbox"/>	Other <input type="checkbox"/>
<b>4.</b>	<b>Requesting Provider Information</b>		
	Provider ID Number:		
	Provider NPI:		
	Requesting Provider Name: (Last, First)		
	Specialty:		
	Phone Number:		
	Fax number:		
	Requesting Provider Address:		
<b>5.</b>	<b>Referred to Provider/Facility Information</b>		
	<b>Type: Office</b> <input type="checkbox"/> <b>OP Hospital</b> <input type="checkbox"/> <b>IP Hospital</b> <input type="checkbox"/> <b>Free Standing Facility</b> <input type="checkbox"/>		
	Provider/Facility ID Number:		
	Provider NPI:		
	Provider/Facility Name:		
	Specialty:		
	Phone Number:		
	Fax Number:		
	Provider/Facility Address:		
<b>6.</b>	<b>Service Requested</b>		
	Planned Date of Service	EDC	(OB Notification)
	Primary ICD-9 Code		Description
	CPT Code(s) or HCPC Code(s)		Description
	Visits/Frequency/Duration		
	Clinical Indications for the Request: (May attach clinical or progress notes. Please include pertinent previous testing results):		
<b>7.</b>	<b>PLAN ADMINISTRATIVE USE ONLY:</b>		
	Service request status:		
	Approved <input type="checkbox"/> Pending <input type="checkbox"/> Denied <input type="checkbox"/>		
	Comments:		

# Ohio Medicaid Managed Care Plan PA Requirements

NOTES: ALL NON-PAR SERVICES REQUIRE PA  
 \*\* See specific MCP website for details

Category	Buckeye Health Plan	CareSource	Molina	OH PARACOUNT	UnitedHealthcare	Additional Notes
<b>ANCILLARY/ DME SERVICES</b> Ambulance & Ambulette Services (except emergency)	Yes	Yes	Yes	Yes	Yes	
Durable Medical Equip	To determine if other DME codes require prior authorization, please refer to: <a href="http://www.bchpohio.com/providers/pre-auth-needed/">http://www.bchpohio.com/providers/pre-auth-needed/</a> Yes	Yes (\$1750)	Yes - refer to Molina's website for list of codes requiring PA	**Yes, per ODM Guidelines for over quantity limits	Yes, over \$1000, enteral, and custom wheelchairs	
Hearing Aids	Yes	Yes	Yes	Yes	Yes	
Home Health Services	Yes, after initial evaluation and first 12 visits	Skilled Home Care Services do not require Prior Auth. If >29day then PA is required. Home Health Aides require Prior Auth	Yes, after 3 skilled nursing visits	Yes after initial evaluation	Yes	
Lispoke Care	Yes	Yes	**No	Yes	No	
Infectables	To determine if other orthotic/prosthetics codes require prior authorization, please refer to: <a href="http://www.bchpohio.com/providers/pre-auth-needed/">http://www.bchpohio.com/providers/pre-auth-needed/</a>	**Yes	**Yes	**Yes	Yes - Bolton, Acthar, IVIG, Xolair, Malera	
Orthotics/Prosthetics	To determine if other orthotic/prosthetics codes require prior authorization, please refer to: <a href="http://www.bchpohio.com/providers/pre-auth-needed/">http://www.bchpohio.com/providers/pre-auth-needed/</a>	Yes (\$1750)	Yes - refer to Molina's website for list of codes requiring PA	No, unless over ODM allowable	Yes, over \$1000	
Therapy -Occupational, Physical & Speech	Yes	Yes > 30	Yes after initial evaluation	No (Yes, if > 30 visits)	No	
Transportation	Yes	Yes - limit 30 one way trips per year	Yes - limit 30 one way trips per year (2 business days notice)	Yes - limit 30 one way per year (48 hours notice)	Yes	
Wound Vacs/ outpatient only	Yes	Yes	Yes	Yes	Yes	
IMPATIENT SERVICES	Hospital Admissions to include TAC/rehab/ospice	Yes	Yes	Yes	Yes	
Nursing Facility Admissions	Yes	Yes	Yes	Yes	Yes	
OUTPATIENT SERVICES	Cardiac Rehab/excludes eval	No PA for outpatient services and per providers	Yes	No	No	
Chemotherapy and Radiation	No - Outpatient Yes - Inpatient	No - Outpatient Yes - Inpatient	No - Outpatient Yes - Inpatient	No - Outpatient Yes - Inpatient	No	
Chiropractic Services	Diagnosis Services at non-contracted facilities	only on non-par providers	Yes	Yes	Yes - under age 21, 30 visits (age 20 and under) no PA	Child = 30 visits, Adult = 15 visits
Diagnosis In Testing:	Yes	Yes	Yes	Yes	Yes	
PEI -SPECT	Yes Visit <a href="http://www.radiol.com">www.radiol.com</a>	Yes	Yes	Yes	Yes	
MRI/MRA, CT Scans	Yes Visit <a href="http://www.radiol.com">www.radiol.com</a>	No- OB US Yes-Fetal NST > 10	Yes	Yes	Yes	
OB Ultrasound	No	No	No	No	No	
Ultrasound (non OB)	No	No	No	No	No	
Dialysis	No	No	Notification Only	No	No	



Copy for STAFF WTB  
MAC

**CABINET FOR HEALTH AND FAMILY SERVICES  
OFFICE OF HEALTH POLICY**

**Steven L. Beshear**  
Governor

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**Audrey Tayse Haynes**  
Secretary

**Emily Whelan Parento**  
Executive Director

**SPECIAL MEMORANDUM  
October 8, 2014**

***Certificate of Need Modernization: Core Principles  
Request for Stakeholder Input***

Health systems across the country are undergoing significant changes in response to myriad factors, including but not limited to the Affordable Care Act. In Kentucky, health reform has highlighted the need to modernize the Certificate of Need (CON) program to better enable health care providers to work toward improved health for all Kentuckians. Thus, in considering changes to the CON program and the State Health Plan in connection with the periodic update process, the Cabinet for Health and Family Services (CHFS) will adopt an holistic approach to revisions, with the vision of achieving the Triple Aim: better value, better care, and population health improvement. To that end, CHFS will be guided by the following core principles:

- *Supporting the Evolution of Care Delivery.* The trend is decisively away from a high-overhead acute/inpatient model to an outpatient-centric model. Thus, the CON program will seek to give health care facilities the ability to respond to market trends in a timely fashion, enabling the continued service of local communities in a changing healthcare environment.
- *Incentivizing Development of a Full Continuum of Care.* Better care, increased value and improved population health depend on an integrated continuum of care in which providers communicate with each other and ensure that patients receive timely, coordinated care in an appropriate setting. Payment structures are evolving to reflect these goals; therefore, the CON program will work to promote and support providers and facilities that seek to develop a robust continuum of care alone or in partnership with others.
- *Incentivizing Quality.* Healthcare is rapidly moving toward adoption of objective quality metrics. Thus, the CON program will seek to support those providers that demonstrate attainment of robust quality indicators.
- *Improving Access to Care.* For a number of reasons, Medicaid members have, on average, a more challenging path toward access to care. Thus, the CON program will seek to incorporate strategies that will incentivize greater access to care for Medicaid members, the newly insured and the remaining uninsured.
- *Improving Value of Care.* As healthcare transitions from a fee-for-service model to a value-based purchasing framework, payers will continue to seek evidence of value in health services. Thus, the CON program will seek to incentivize both price transparency and demonstrable value from health professionals and facilities.

- *Promoting Adoption of Efficient Technology.* Increased adoption of technologies such as electronic medical records, participation in information sharing platforms such as the Kentucky Health Information Exchange, and participation in large-scale data projects such as an All Payer Claims Database are critical elements of a modernized, higher quality and more efficient health system. Thus, the CON program will seek to incentivize adoption of technologies deemed to further improve value in Kentucky's health system.
- *Exempting Services for which CON is no longer necessary.* Kentucky regulates via CON many services that even CON states exempt. Thus, Office of Health Policy will seek to focus on strategies to modernize Kentucky's CON program to be more reflective of modern healthcare trends.

With these core principles in mind, CHFS requests feedback from all interested stakeholders regarding possible strategies for and changes to the CON program that would further the implementation of the identified principles.

While feedback in the form of specific regulatory language amendments/changes is acceptable, it should not be submitted without an accompanying narrative clearly identifying (1) reasons for the proposed changes, and (2) specific identification of how the proposed change would help further the implementation of one or more of the identified core principles.

Please also note that specific regulatory language amendments are not the preferred form of comment at this stage of the CON modernization process. Rather, we seek to learn from stakeholders the barriers and opportunities that they experience in the CON program as they evolve their practices in response to the Affordable Care Act and broader healthcare trends. For example, in developing a robust continuum of care, how does the CON program help or hinder your efforts? Policy papers are strongly encouraged, as are specific and data-supported responses to the Deloitte Healthcare Facility Capacity Report released in December 2013, available at:

<http://healthbenefitexchange.ky.gov/Pages/news.aspx?wid=13>

Following receipt and consideration of all suggestions, it is the intent of CHFS to convene multiple stakeholder listening sessions to discuss opportunities to improve the CON program prior to undertaking any substantive revisions.

All input should be submitted by November 30, 2014 to the Office of Health Policy:

Office of Health Policy  
c/o Diona Mullins, Policy Advisor  
Cabinet for Health & Family Services  
275 E. Main Street, 4W-E  
Frankfort, KY 40621

Email submissions are also acceptable; however, please ensure that Ms. Mullins confirms receipt of your electronic submission.

[Diona.Mullins@ky.gov](mailto:Diona.Mullins@ky.gov)

Please contact Ms. Mullins at 502.564.9592 with any questions.



## ICD-10 Implementation Progress Attestation

Every quarter, the primary points of contact (POC) for the state Medicaid agency's (SMA) ICD-10 project team are asked to complete a self-reported, ICD-10 readiness assessment (RA). CMS is requesting assurance from the State Medicaid Director that the responses in the RA accurately reflect the current status and progress of ICD-10 implementation in each SMA.

Attached are the results of the September 2014 Readiness Assessment for your SMA. Please review them carefully. If you have questions, please refer them to your SMA ICD-10 POC.

Please sign, scan and e-mail this document to [medicaidICD10@Noblis.org](mailto:medicaidICD10@Noblis.org) by no later than October 17, 2014.

I attest that I have seen the results of the September 2014 Readiness Self-Assessment for my State Medicaid Agency, and I verify that these results reflect our ICD-10 implementation progress as of September 30, 2014.

LAWRENCE KISSNER  
Print Name

COMMISSIONER  
Title / SMA POC

  
Signature

10/15/14  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Director,  
Title / SMA

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

# ICD-10 NATIONAL IMPLEMENTATION STATUS

## KENTUCKY: ASSESSMENT RESULTS

### READINESS ASSESSMENT SUMMARY

Current Phase	External Testing Phase	Numerical Score		High Level Results		
		Last Updated	Actual Score	Possible Score	State Risk Percentage	State Risk Level
Overall Readiness			262	283	92.58%	Low Risk (green)
<b>General Readiness</b>						
<b>General Readiness</b>	9/19/2014 1:52:00 PM		35	41	85.37%	Low Risk (green)
<b>Awareness Phase</b>	9/19/2014 2:02:00 PM		40	40	100%	Low Risk (green)
<b>Assessment Phase</b>	9/19/2014 2:05:00 PM		42	42	100%	Low Risk (green)
<b>Remediation Phase</b>	9/19/2014 2:39:00 PM		67	67	100%	Low Risk (green)
<b>Testing Phase</b>	9/19/2014 2:42:00 PM		78	93	83.87%	Low Risk (green)
<b>Transition Phase</b>	9/19/2014 2:32:00 PM		0	0	100%	Low Risk (green)

Legend	0-64.9%	65-79.9%	80-100%
State Risk			
Risk Level	High Risk (red)	Moderate Risk (yellow)	Low Risk (green)

	Inputs			Detailed Results	
	Criticality Consequence of Skipping Activity	Expected Level of Progress Based on CMS Timeline Range: 1-7	State Response Self Reported Range: 1-7, N/A	State Timeliness Based on Inputs	State Risk Level Aggregate Risk Based on Timeliness of Activities
<b>General Readiness Last Updated: 09/19/2014</b>					Low Risk (green)
1. The information submitted in this assessment accurately represents the SMA's ICD-10 implementation progress. Please provide your full name and title:	Free Response	-	USHA KOMMINENI ICD-10 PROJECT MANAGER	Free Response	
2. Please indicate your confidence level that the State Medicaid Agency (SMA) will meet the ICD-10 compliance date of October 1, 2015.	Percentage	-	100%	Percentage	
3. If the SMA is not on track to meet the compliance date, please explain why.	Free Response	-		Free Response	
4. What percent of the SMA's processed and paid claims are based on ICD codes?	Percentage	-	5%	Percentage	
5. Please provide additional detail regarding processed and paid claims based on ICD-10 coding.	Free Response	-		Free Response	
6. What percent of the SMA's total claims payment are based on ICD codes?	Percentage	-	5%	Percentage	
7. Please provide additional detail regarding claims payment based on ICD-10 coding.	Free Response	-		Free Response	
8. Will the SMA able to accept electronic claims with ICD-9 and ICD-10 coding based on the dates of service and dates of discharge using Version 5010 transactions on October 1, 2015? (Explanation - claims with ICD-9 codes will need to be accepted for services prior to 10/1/2015 and claims with ICD-10 codes will need to be accepted for services on or after 10/1/2015.)	Yes/No	-	Yes	Yes/No	
9. Please describe the SMA's risk mitigation plan if unable to accept electronic claims with ICD-9 and ICD-10 coding based on the dates of service and dates of discharge using Version 5010 transactions.	Free Response	-	If the state unable to accept electronic claims the state will accept and process paper claims	Free Response	
10. Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	If mitigation strategy implemented the impact will be significant on the department and the contracted fiscal agent in terms of processing time and budget, overrun and resource allocation	Free Response	
11. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-	6	# Months	
12. Will the SMA have the ability to adjudicate diagnosis dependent claims and use the dependent grouper on October 1, 2015?	Yes/No	-	Yes	Yes/No	
13. Please describe what the SMA's risk mitigation plan is if unable to adjudicate diagnosis dependent claims and use the dependent grouper.	Free Response	-	Use a crosswalk mapper tool to crosswalk the ICD-10 codes to ICD-9 and process the claims the same way it is currently done in MMIS system	Free Response	
14. Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	If mitigation strategy implemented the impact will be significant on the department and the contracted fiscal agent in terms of processing time and budget, overrun and resource allocation	Free Response	
15. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-		# Months	
16. Will the SMA have the ability to pay professional providers for claims with ICD-9 and ICD-10					

# ICD-10 NATIONAL IMPLEMENTATION STATUS

	Inputs			Detailed Results	
	Criticality Consequence of Skipping Activity	Expected Level of Progress Based on CMS Timeline Range: 1-7	State Response Self Reported Range: 1-7, N/A	State Timeliness Based on Inputs	State Risk Level Aggregate Risk Based on Timeliness of Activities
17. Please describe the SMA's risk mitigation plan if unable to pay professional providers for claims with ICD-9 and ICD-10 codes based on the dates of service and dates of discharge using Version 5010 transactions.	Free Response	-	Will accept paper claims/manual processing	Free Response	
18. Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	If implemented there will be a huge impact on budget, processing time and resources	Free Response	
19. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-		# Months	
20. Will the SMA have the ability to pay institutional providers for claims with ICD-9 and ICD-10 codes based on the dates of service and dates of discharge using Version 5010 transactions on October 1, 2015?	Yes/No	-	Yes	Yes/No	
21. Please describe the SMA's risk mitigation plan if unable to pay institutional providers for claims with ICD-9 and ICD-10 codes based on the dates of service and dates of discharge using Version 5010 transactions.	Free Response	-	Will accept paper claims/manual processing	Free Response	
22. Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	If implemented, there will be a huge impact on budget, processing time and resources	Free Response	
23. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-		# Months	
24. Will the SMA have the ability to pay Managed Care Organizations/Entities for claims with ICD-9 and ICD-10 codes based on the dates of service and dates of discharge using Version 5010 transactions on October 1, 2015?	Yes/No	-	Yes	Yes/No	
25. Please describe the SMA's risk mitigation plan if unable to pay Managed Care Organizations/Entities for claims with ICD-9 and ICD-10 codes based on the dates of service and dates of discharge using Version 5010 transactions.	Free Response	-	MCOs paid PMPM and the state accepts adjudicated encounters (paid, denied, adjusted). If unable to edit against electronic submission, data validity at risk	Free Response	
Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	If implemented, there will be a huge impact on budget, processing time and resources	Free Response	
27. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-		# Months	
28. Will the SMA be able to complete coordination of benefit processes and exchange claims with partners including Medicare and others on October 1, 2015?	Yes/No	-	Yes	Yes/No	
29. Please describe the SMA's risk mitigation plan if unable to complete coordination of benefit processes and exchange claims with partners; all types including Medicare and others. (Please describe the risk mitigation plan by specific partner).	Free Response	-	benefit data processing is not dependent on ICD codes. Medicare crossover claims processing may be delayed if system remediation issues happen and delay ICD10 implementation	Free Response	
30. Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	Budget, processing time and resource drain	Free Response	
31. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-		# Months	
32. Will the SMA have the ability to create and send MSIS and/or T-MSIS reports for ICD-10 claims on October 1, 2015?	Yes/No	-	Yes	Yes/No	
33. Please describe the SMA's risk mitigation plan if unable to create and send MSIS and/or T-MSIS reports for ICD-10 claims. Please describe the risk mitigation for both MSIS and T-MSIS if different.	Free Response	-	The state will continue to use the old method for submitting the MSIS report	Free Response	
34. Please describe the impact to the SMA if the mitigation strategy is put into action?	Free Response	-	Delay of the report submission due to more processing time	Free Response	
35. If applicable, please describe how long the SMA intends to use the mitigation strategy?	# Months	-		# Months	
36. Does the SMA have a portal for providers to submit claims?	Yes/No	-	Yes	Yes/No	
36a. Will the provider portal be ICD-10 ready by the compliance date?	Yes/No	-	No	Yes/No	
36b. What type of providers can submit claims to the portal?	Checkbox	-	All providers All DMS enrolled providers		
36c. Please provide the date you completed or anticipate completion of Level 1 Testing for the provider portal?	Date	12/31/2013	04/13/2015	Date	
36d. Please provide the date you completed or anticipate completion of Level 2 Testing for the provider portal?	Date	10/01/2014	06/15/2015	Date	
36e. Please provide the date you completed or anticipate completion of Level 3 Testing for the provider portal?	Date	06/30/2015	08/10/2015	Date	
Does the SMA provide any free/low cost billing software (e.g., ACS' WINASAP5010, ProAce PC32, etc.) to its providers?	Yes/No	-	No	Yes/No	
37a. Please provide the name and version of the free/low cost billing software provided by the SMA or Fiscal Agent.	Free Response	-		Free Response	
37b. Please provide the date you completed (or anticipate completion of) LEVEL 1 Testing or the free/low cost billing software.	Date	12/31/2013		Date	
37c. Please provide the date you completed (or anticipate completion of) LEVEL 2 Testing or the free/low cost billing software.	Date	10/01/2014		Date	

# ICD-10 NATIONAL IMPLEMENTATION STATUS

	Inputs			Detailed Results	
	Criticality Consequence of Skipping Activity	Expected Level of Progress Based on CMS Timeline Range: 1-7	State Response Self Reported Range: 1-7, N/A	State Timeliness Based on Inputs	State Risk Level Aggregate Risk Based on Timeliness of Activities
38. Has the SMA established an EXECUTIVE SPONSOR that is committed to assist and monitor ICD-10 implementation?	Medium	Yes	Yes	Timely (green)	
39. Is the SMA currently operating an ICD-10 STEERING COMMITTEE to coordinate, monitor, and track activities and risks, and escalate issues?	Medium	c. The steering committee meets regularly to discuss ICD-10 OR d. Not applicable (in situations where an overarching SMA Steering Committee addresses ICD-10 as a component of multiple projects)	c. The steering committee meets regularly to discuss ICD-10	Timely (green)	
40. Has the SMA assigned an ICD-10 TEAM LEAD, BUSINESS LEAD, and TECHNICAL LEAD?	Medium	Team Lead, Business Lead, or Technical Lead	Team Lead Business Lead Technical Lead	Timely (green)	
41. Does the SMA have a working ICD-10 GOVERNANCE STRUCTURE?	Medium	c. Governance structure defined and fully operational	c. Governance structure defined and fully operational	Timely (green)	
42. Has the SMA completed all of the needed APDs for ICD-10 Implementation?	High	c. Yes, the SMA has completed all the needed APDs	b. The SMA has submitted the needed APDs and is awaiting CMS approval	Overdue (red)	
42a. What type of APD will be submitted?	Free Response	-		Free Response	
42b. When will the SMA submit the APD to CMS?	Date	-		Date	
42c. What will the additional APD(s) cover?	Free Response	-		Free Response	
43. Is the SMA still processing Version 4010 transactions?	Critical	No	No	Timely (green)	
43a. If the SMA is processing/receiving Version 4010 transactions, what percentage of the SMA's claims are 4010-based?	Percentage	-		Percentage	
43b. If the SMA is still processing Version 4010 transactions, please explain what will happen after 10/1/2015.	Free Response	-		Free Response	
43c. On what date will the SMA stop processing/receiving Version 4010 transactions?	Date	-		Date	
44. What General issue(s) is the SMA experiencing with ICD-10 where CMS/Noblis could support the SMA's efforts?	Free Response	-		Free Response	

# ICD-10 NATIONAL IMPLEMENTATION STATUS

	Criticality	Expected Level of Progress	State Response	State Timeliness	State Risk Level
Awareness Phase Readiness Last Updated: 09/19/2014					Low Risk (green)
1. What was the actual/anticipated start date for the Awareness Phase?	Date	09/01/2010	07/01/2011	Date	
2. What was the actual/anticipated end date of the awareness phase?	Date	04/01/2016	10/01/2012	Date	
3. What is the percent complete of the Awareness phase?	Critical	75%	100%	Timely (green)	
4. What activities remain to be completed for the Awareness Phase?	Free Response	-		Free Response	
5. Has the SMA developed a Communication plan for ICD-10? (Explanation -The plan should detail the roles and responsibilities of the team and explain how and what information will be distributed internally and externally.)	High	c. Executing the communication plan and regularly communicating progress	c. Executing the communication plan and regularly communicating progress	Timely (green)	
6. What is the level of engagement of the SMA's leadership in the ICD-10 implementation?	Low	c. Fully Engaged	c. Fully Engaged	Timely (green)	
7. What percentage of ICD-10 TRAINING has been completed for SMA staff?	Medium	75%	100%	Timely (green)	
8. What is the date that ICD-10 training for staff was or will be completed?	Date	-	06/16/2014	Date	
9. What is the progress of the SMA's PROVIDER OUTREACH ACTIVITIES?	Medium	75%	100%	Timely (green)	
10. State the progress of the SMA's Providers' readiness for ICD-10. (Put 0% if unknown.)	Percentage	-	50%	Percentage	
11. Please describe how the SMA is monitoring the readiness of their Providers?	Free Response	-	Surveys and alerts	Free Response	
12. Please provide any additional comments on Provider's readiness.	Free Response	-		Free Response	
13. What is the progress of the SMA's outreach activities with Trading Partners' and Vendors?	Medium	90%	90%	Timely (green)	
14. State the progress of the SMA's Trading Partners' and Vendor's readiness for ICD-10 if known. (Put 0% if unknown.)	Percentage	-	85%	Percentage	
15. Please describe how the SMA is monitoring the readiness of their Trading Partners and Vendors?	Free Response	-	Weekly status reports on project progress, risks/issues log	Free Response	
16. Please describe the external awareness activities that have been completed to date.	Free Response	-	Website updates, provider banner notices, provider workshops, MCO collaboration calls	Free Response	
16a. Please describe the training/outreach that your SMA has completed for Small Physician Practices (up to 10 physicians).	Free Response	-	Letters and Information on website	Free Response	
16b. Please describe the training/outreach that your SMA has completed for Large Physician Practices (11 or more physicians).	Free Response	-	Letters and Information on website	Free Response	
16c. Please describe the training/outreach that your SMA has completed for Hospitals.	Free Response	-	Letters and Information on website	Free Response	
16d. Please describe the training/outreach that your SMA has completed for trading partners.	Free Response	-	Letters and Information on website	Free Response	
16e. Please describe the training/outreach that your SMA has completed for Vendors.	Free Response	-	Letters and Information on website	Free Response	
17. What CMS/Noblis support would be helpful in support of the SMA's activities in the Awareness Phase?	Free Response	-		Free Response	

# ICD-10 NATIONAL IMPLEMENTATION STATUS

	Criticality	Expected Level of Progress	State Response	State Timeliness	State Risk Level
<b>Assessment Phase Readiness Last Updated: 09/19/2014</b>					Low Risk (green)
1. What was the actual/anticipated start date for the Assessment Phase?	Date	09/01/2010	01/01/2013	Date	
2. What was the actual/anticipated end date of the Assessment phase?	Date	06/30/2012	02/01/2014	Date	
3. What is the percent complete of the Assessment phase?	Critical	100%	100%	Timely (green)	
4. Has the SMA created an ICD-10 project plan?	High	Yes	Yes	Timely (green)	
4a. Has the SMA been able to adhere to the ICD-10 project plan?	Yes/No	-	Yes	Yes/No	
4b. If SMA activities have varied from the project plan please explain the impact to the plan.	Free Response	-		Free Response	
5. Has the SMA performed an ICD-10 IMPACT ASSESSMENT?	Critical	c. Impact Assessment has been completed	c. Impact Assessment has been completed	Timely (green)	
5a. If the SMA has not started the Impact Assessment, when will it be started?	Date	-		Date	
5b. If the SMA has not completed the Impact Assessment, when will it be completed?	Date	-		Date	
6. Has the SMA developed a Policy and Business Process Remediation Strategy?	High	Yes	Yes	Timely (green)	
6a. Please explain the chosen remediation strategy.	Free Response	-	like for like utilizing mixture of mapping and native redefinition	Free Response	
6b. When does the SMA plan on developing the remediation strategy?	Date	-		Date	
6c. Please state any issues the SMA might have when developing it (if any).	Free Response	-		Free Response	
7. Please select the systems remediation strategy that the SMA is using for ICD-10 implementation.	High* Scored as part of Remediation Section	Native Processing	Native Processing	Timely (green)	
7a. Please explain the chosen remediation strategy.	Free Response	-		Free Response	
7b. On what date will your SMA transition to Native Processing?	Date	-		Date	
7c. Please state any issues the SMA might have when developing it (if any).	Free Response	-		Free Response	
8. What activities remain to be completed for the Assessment Phase?	Free Response	-		Free Response	
9. What can CMS/Noblis do to support the SMA's efforts in the Assessment Phase?	Free Response	-		Free Response	

# ICD-10 NATIONAL IMPLEMENTATION STATUS

	Criticality	Expected Level of Progress	State Response	State Timeliness	State Risk Level
Mediation Phase Readiness Last Updated: 09/19/2014					Low Risk (green)
1. What was the actual/anticipated start date for the Remediation Phase?	Date	06/01/2011	06/01/2013	Date	
2. What was the actual/anticipated end date of the Remediation phase?	Date	12/31/13	07/01/2014	Date	
3. What progress has the SMA made in updating the MMIS SYSTEMS AND FILES to support and use ICD-10 codes? (Testing Levels Definitions: Level 1 Testing = internal testing limited to a specific system; Level 2 Testing = internal testing with other state system(s); Level 3 Testing = external testing, in a production-like-mode, with systems outside of the SMA.)	Critical	e2. Performed Level 2 Testing	e2. Performed Level 2 Testing	Timely (green)	
4. If the SMA is operating a legacy MMIS system, when is the SMA scheduled to update it to support ICD-10?	Date	-		Date	
5. Is the SMA operating a State-run and State-owned MMIS system or operating a Contractor-run and State-owned MMIS system?	Free Response	-	b. Contractor-run MMIS system	Free Response	
5a. If the SMA is using a vendor and/or contractor for the MMIS, Please provide vendor name:	Free Response	-	Hewlett-Packard	Free Response	
6. What percent complete is the SMA with developing change requests?	Low	100%	100%	Timely (green)	
7. What percent complete is the SMA with developing requirements?	High	100%	100%	Timely (green)	
8. What percent complete is the SMA with implementing policy updates to support ICD-10?	Critical	100%	95%	Timely (green)	
9. What percent complete is the SMA with implementing process updates to support ICD-10?	High	100%	100%	Timely (green)	
10. What percent complete is the SMA with implementing system updates to support ICD-10?	Critical	100%	100%	Timely (green)	
11. What activities remain to be completed for the Remediation Phase?	Free Response	-		Free Response	
12. What can CMS/Noblis do to help with the remediation phase?	Free Response	-		Free Response	

# ICD-10 NATIONAL IMPLEMENTATION STATUS

Testing Phase Readiness Last Updated: 09/19/2014

	Criticality	Expected Level of Progress	State Response	State Timeliness	State Risk Level
					Low Risk (green)
1. What was the actual/anticipated start date for Internal Testing?	Date	10/01/2012	01/14/2014	Date	
1a. What was/is your SMA's actual/anticipated START DATE for Level 1 testing?	Date	10/01/2012	06/16/2014	Date	
1b. What was/is your actual/anticipated START DATE for Level 2 testing?	Date	10/01/2012	08/18/2014	Date	
2. What was the actual/anticipated end date for Internal Testing?	Date	10/01/2014	07/14/2014	Date	
2a. What was/is your SMA's actual/anticipated END DATE for Level 1 testing?	Date	12/31/2013	07/14/2014	Date	
2b. What was/is your actual/anticipated END DATE for Level 2 testing?	Date	10/01/2014	08/15/2014	Date	
3. What is the percent complete of the Internal Testing?	Percentage	-	100%	Percentage	
3a. What percentage of Level 1 testing has your SMA completed?	Critical	100%	100%	Timely (green)	
3b. What percentage of Level 2 testing has your SMA completed?	Critical	100%	100%	Timely (green)	
4. What percent complete is the SMA with creating Test Scripts?	Percentage	-	100%	Percentage	
5. Will the SMA perform system testing?	Yes/No	-	Yes	Yes/No	
5a. What percent of System testing has the SMA completed?	High	100%	100%	Timely (green)	
6. Will the SMA perform Regression testing?	Yes/No	-	Yes	Yes/No	
6a. What percent of Regression Testing has the SMA completed?	High	100%	75%	Overdue (red)	
7. Will the SMA perform User Acceptance Testing?	Yes/No	-	Yes	Yes/No	
7a. What percent of User Acceptance Testing has the SMA completed?	Medium	100%	50%	Overdue (red)	
8. Will the SMA perform Non-functional testing?	Yes/No	-	Yes	Yes/No	
8a. What percent of Non-functional testing has the SMA completed?	Low	100%	85%	Overdue (red)	
9. What activities remain to be completed for Internal Testing?	Free Response	-		Free Response	
9a. What activities remain to be completed for Level 1 testing?	Free Response	-	None	Free Response	
9b. What activities remain to be completed for Level 2 testing?	Free Response	-	Some sister Agencies	Free Response	
10. Please provide any additional information about the SMA's Internal Testing.	Free Response	-		Free Response	
11. What is/was the actual/anticipated START DATE for Level 3 Testing (external testing, in a production-like-mode, with systems outside of the SMA – e.g., end-to-end testing with each trading partner)?	Date	01/01/14	08/18/2014	Date	
11a. What is being done to ensure the SMA has sufficient testing partners for Level 3 Testing?	Free Response	-	DMS contacting MCO's , Providers and Trading Partners for level 3 testing	Free Response	
12. What was the actual/anticipated end date for External Testing?	Date	06/30/2015	09/30/2014	Date	
13. Has the SMA created a list of Providers, Vendors, and Trading Partners that are mission-critical and will be used in testing?	High	c. Completed identification	c. Completed identification	Timely (green)	
14. Please indicate all external stakeholders with whom the SMA will conduct testing.	Checkbox	-	Small Physician Practices (up to 5 physicians) Large Physician Practices (6 or more physicians) Hospitals Trading partners Vendors	Free Response	
15. What percent complete is the SMA in creating an External Test Plan?	High	100%	100%	Timely (green)	
16. What percent of System Integration testing, review test results and address defects and document test results in Test Plan has the SMA complete?	Medium	100%	100%	Timely (green)	
17. What percent of Connectivity Testing with any new Trading Partner(s) and update results in the Test Plan has the SMA performed?	Low	25%	50%	Timely (green)	
18. What percentage of the Level 3 testing has the SMA completed?	High	25%	75%	Timely (green)	
19. What activities remain to be completed for the Level 3 testing?	Free Response	-	Systems outside of the SMA	Free Response	
20. Please provide any additional information about the SMA's Level 3 testing.	Free Response	-		Free Response	
21. What support can CMS/Noblis provide to help with the testing phase?	Free Response	-		Free Response	

# ICD-10 NATIONAL IMPLEMENTATION STATUS

Transition Phase Readiness Last Updated: 09/19/2014

	Criticality	Expected Level of Progress	State Response	State Timeliness	State Risk Level
1. What was the actual/anticipated start date for the Transition Phase?	Date	03/01/2015	10/01/2015	Date	Low Risk (green)
2. What was the actual/anticipated end date for the Transition Phase?	Date	04/01/2016	03/31/2016	Date	
3. What is the percent complete of the Transition Phase?	Percentage	0%	0%	Percentage	
4. What activities remain to be completed for the Transition Phase?	Free Response	-		Free Response	
5. What support can CMS/Noblis provide to help with the transition phase?	Free Response	-		Free Response	
6. Has the SMA planned for post-implementation support?	Yes/No	-	Yes	Yes/No	
7. What activities does the SMA have planned for post-implementation support?	Free Response	-	Increasing Call centers, Early warning indicators and regular monitoring	Free Response	
8. What support can CMS/Noblis provide to help with the post-implementation support?	Free Response	-		Free Response	



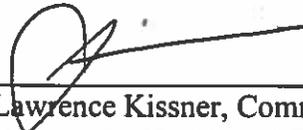
**FINAL DETERMINATION OF THE COMMISSIONER OF THE  
DEPARTMENT FOR MEDICAID SERVICES OF THE  
KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES  
ACCEPTING THE RECOMMENDATION  
OF THE PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE**

Pursuant to KRS 205.564(9) and 907 KAR 1:019E, Section 8, after reviewing the recommendations of the Pharmacy and Therapeutics Advisory Committee ("Committee") made as a result of its discussions and meeting conducted on September 18, 2014, in Frankfort, Kentucky, and in consultation with the Department for Medicaid Services and any exceptions filed thereto in accordance with the provisions of 907 KAR 1:019E:

I hereby **ACCEPT** and **ADOPT** the Committee's September 18, 2014, recommendations in full, which are attached hereto.

This determination is final and appealable.

**SO ORDERED** this the 10<sup>th</sup> day of October, 2014.

  
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Lawrence Kissner, Commissioner,  
Cabinet for Health and Family Services,  
Department for Medicaid Services

**Commissioner for the Department for Medicaid Services  
Selections for Preferred Products**

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for the Department for Medicaid Services based on the September 18, 2014 Pharmacy and Therapeutics (P&T) Advisory Committee Meeting.

Description of Recommendation	Final Decision (s)
<p><b><u>New Products to Market: Adempas<sup>®</sup></u></b> Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension; however, approve riociguat (Adempas<sup>®</sup>) if the following are true:</p> <ul style="list-style-type: none"> <li>• Diagnosis of PAH (WHO Group I) after trial and failure of two preferred products; OR</li> <li>• Diagnosis of CTEPH (WHO Group 4) functional class II or III deemed inoperable or with residual PH after undergoing pulmonary endarterectomy.</li> </ul>	<p>The final PDL placement will be determined after a re-review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Orenitram<sup>™</sup></u></b> Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Zontivity<sup>™</sup></u></b> Place this product non preferred in the PDL class titled Platelet Inhibitors; however, approve Zontivity<sup>™</sup> for a diagnosis of history of myocardial infarction (MI) or peripheral artery disease (PAD) WITHOUT a history of stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS), gastrointestinal (GI) bleed, or peptic ulcer. Patients must also be taking aspirin and/or clopidogrel concomitantly.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Velporo<sup>®</sup></u></b> Place this product non preferred in the PDL class titled Phosphate Binders.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Tanzeum<sup>™</sup></u></b> Place this product non preferred in the PDL class titled GLP-1 Receptor Agonists.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Otezla<sup>®</sup></u></b> Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Immunomodulators.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Entyvio<sup>™</sup></u></b> Place this product non preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Zykadia<sup>™</sup></u></b> Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>

Description of Recommendation	Final Decision (s)
<p><b><u>New Products to Market: Zohydro ER™</u></b> Place this product non preferred with appropriate quantity limits in the PDL class titled Narcotics: Long-Acting.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Evzio™</u></b> Evzio™ will be limited to 4 auto injectors per prescription and will only be approved in the following circumstances:</p> <ul style="list-style-type: none"> <li>▪ Patient or care-giver is administering medication outside of a healthcare facility (such as a personal residence or school); AND</li> <li>▪ Patient or active care-giver is unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension; AND</li> <li>▪ The prescriber has completed and submitted with the prior approval request the Opioid Overdose Risk Assessment Checklist Form. The form can be found at: <a href="http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf">http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf</a>; AND</li> <li>▪ If the diagnosis is substance abuse, dependence and/or addiction, the patient is receiving addiction counseling services; such as psychosocial therapy from a Substance Abuse provider. Documentation must be provided to include provider name, type of provider, and provider phone number.</li> </ul>	<p>The final criteria will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Aptiom®</u></b> Place this product non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Hetlioz®</u></b> Place this product non preferred with appropriate quantity limits in the PDL class titled Sedative Hypnotics; however, only approve tasimelteon (Hetlioz®) for a diagnosis of Non-24-hour sleep-wake disorder (“non-24”) in patients who are totally blind.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Anoro™ Ellipta™</u></b> Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents; however, approve Anoro™ Ellipta™ for a diagnosis of COPD after trial and failure of an inhaled long-acting bronchodilator (a LABA or an anticholinergic).</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b><u>New Products to Market: Sivextro™</u></b> Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Oxazolidinones.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>

<b>Description of Recommendation</b>	<b>Final Decision (s)</b>
<p><b>New Products to Market: Luzu<sup>®</sup></b> Place this product non preferred in the PDL class titled Topical Antifungal Agents.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b>New Products to Market: Jublia<sup>®</sup></b> Place this product non preferred in the PDL class titled Topical Antifungal Agents; however, only approve efinaconazole (Jublia<sup>®</sup>) for a diagnosis of toenail onychomycosis after trial and failure of one other agent indicated for the treatment of onychomycosis.</p>	<p>The final PDL placement will be determined after a review of this product at the next P&amp;T meeting.</p>
<p><b>Topical Antifungal Agents</b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least agents representing multiple mechanisms of action as well as a combination product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. Before utilization, the combination product miconazole/zinc oxide should be subject to trial and failure of conventional therapies for diaper dermatitis.</li> <li>4. For any new chemical entity in the Topical Antifungal Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b>Selected Preferred Agent (s)</b> clotrimazole solution, cream econazole ketoconazole shampoo, cream nystatin cream, ointment, powder nystatin/triamcinolone cream, ointment</p> <p><b>Non Preferred Agent (s)</b> Bensal HP<sup>®</sup> Ciclodan<sup>®</sup> cream/kit Ciclodan<sup>™</sup> solution ciclopirox clotrimazole /betamethasone CNL-8<sup>™</sup> Ecoza<sup>™</sup> Ertaczo<sup>®</sup> Exelderm<sup>®</sup> Extina<sup>®</sup> ketoconazole foam Ketodan<sup>™</sup> Loprox<sup>®</sup> Lotrimin<sup>®</sup> Lotrisone<sup>®</sup> Mentax<sup>®</sup> Naftin<sup>®</sup> Nizoral Shampoo<sup>®</sup> Oxistat<sup>®</sup> Pediaderm AF<sup>®</sup> Pedioprox-4<sup>™</sup> Penlac<sup>®</sup> Vusion<sup>®</sup> Xolegel<sup>®</sup></p>

<b>Description of Recommendation</b>	<b>Final Decision (s)</b>
<p><b><u>Topical Antiviral Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Antiviral Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b> acyclovir ointment</p> <p><b><u>Non Preferred Agent (s)</u></b> Denavir<sup>®</sup> Xerese<sup>™</sup> Zovirax<sup>®</sup> cream Zovirax<sup>®</sup> ointment</p>
<p><b><u>Topical Antibiotic Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be mupirocin ointment, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Antibiotic Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b> Bactroban<sup>®</sup> cream gentamicin 0.1% cream, ointment mupirocin ointment neomycin/polymyxin/pramoxine</p> <p><b><u>Non Preferred Agent (s)</u></b> Altabax<sup>™</sup> Bactroban<sup>®</sup> ointment Centany<sup>®</sup> mupirocin cream Triple Antibiotic<sup>®</sup></p>
<p><b><u>Topical Antiparasitic Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be permethrin 5% cream, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Antiparasitic Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b> Eurax<sup>®</sup> Natroba<sup>®</sup> permethrin 5% cream Sklice<sup>®</sup></p> <p><b><u>Non Preferred Agent (s)</u></b> Elimite<sup>™</sup> lindane malathion Ovide<sup>®</sup> spinosad Ulesfia<sup>®</sup></p>

Description of Recommendation	Final Decision (s)
<p><b><u>Topical Psoriasis Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. For any new chemical entity in the Topical Psoriasis Agents, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b>  calcipotriene  salicylic acid shampoo, gel  urea cream</p> <p><b><u>Non Preferred Agent (s)</u></b>  Aluvea<sup>®</sup>  Bensal HP<sup>®</sup>  BP 50%  calcipotriene/betamethasone  Calcitrene<sup>™</sup>  calcitriol ointment  Cem-Urea<sup>®</sup>  Dovonex<sup>®</sup>  Latrix<sup>®</sup>  Latrix XM<sup>®</sup>  Remeven<sup>®</sup>  Salacyn<sup>®</sup> lotion, cream  salicylic acid cream, lotion, 26% liquid27.5%  liquid, combo pkg, kit  Salex<sup>®</sup> shampoo, combo pkg, kit  Sorilux<sup>™</sup>  Taclonex<sup>®</sup> ointment, suspension  Taclonex<sup>®</sup> Scalp  Tazorac<sup>®</sup>  Umecta<sup>®</sup> Kit, foam, emulsion, suspension  Umecta<sup>®</sup> PD suspension, emulsion  Uramaxin<sup>®</sup>  Uramaxin<sup>®</sup> GT  urea suspension, gel, lotion, nail film suspension,  kit, foam, emulsion  Vectical<sup>™</sup>  X-Viate<sup>®</sup></p>
<p><b><u>Oral Psoriasis Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require prior authorization.</li> <li>3. For any new chemical entity in the Oral Psoriasis Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b>  OxSORALEAN-Ultra<sup>®</sup>  Soriatane<sup>®</sup></p> <p><b><u>Non Preferred Agent (s)</u></b>  8-MOP<sup>®</sup>  acitretin  methoxsalen</p>

Description of Recommendation	Final Decision (s)
<p><b><u>Oral Acne Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require prior authorization.</li> <li>3. For any new chemical entity in the Oral Acne Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b></p> <p>Amnesteem<sup>®</sup>  Claravis<sup>™</sup>  Myorisan<sup>™</sup>  Sotret<sup>®</sup>  Zenatane<sup>™</sup></p> <p><b><u>Non Preferred Agent (s)</u></b></p> <p>Absorica<sup>™</sup></p>
<p><b><u>Otic Antibiotics</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity otic quinolone, one otic quinolone/steroid combination product and one non-quinolone combination product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Otic Antibiotics class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b></p> <p>Ciprodex<sup>®</sup> Otic  hydrocortisone 1%/neomycin sulfate 5 mg/polymyxin B 10,000 units solution and suspension  ofloxacin 0.3% solution</p> <p><b><u>Non Preferred Agent (s)</u></b></p> <p>Cetraxal<sup>®</sup>  ciprofloxacin 0.2%  Cipro HC<sup>®</sup> Otic  Coly-mycin<sup>®</sup> S  Cortisporin<sup>®</sup> solution  Cortisporin<sup>®</sup>-TC  Floxin<sup>®</sup> Otic</p>

<b>Description of Recommendation</b>	<b>Final Decision (s)</b>
<p><b><u>Otic Anti-Infective/Anesthetics/Anti-Inflammatories</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Otic Anti-Infective/Anesthetics/Anti-Inflammatories class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b></p> <p>acetic acid antipyrine/benzocaine</p> <p><b><u>Non Preferred Agent (s)</u></b></p> <p>Acetasol HC<sup>®</sup> acetic acid/hydrocortisone acetic acid in aluminum acetate Aralagan<sup>®</sup> Aurodex<sup>®</sup> Auroguard<sup>®</sup> chloroxylenol/pramoxine/hydrocortisone Dermotic<sup>®</sup> Dolotic<sup>®</sup> fluocinolone 0.01% oil Myoxin<sup>®</sup> Neotic<sup>®</sup> Otic Care<sup>®</sup> Oto-End 10<sup>®</sup> Otozin<sup>™</sup> Pinnacaine<sup>®</sup> Pramotic<sup>®</sup> Pramoxine HC<sup>®</sup> PR Otic<sup>®</sup> Trioxin<sup>®</sup> Vosol<sup>®</sup> Vosol<sup>®</sup> HC</p>
<p><b><u>Alpha Blockers for BPH</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, one of which should be highly selective for the alpha receptors in the genitourinary tract, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Alpha Blockers for BPH class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b></p> <p>alfuzosin ER doxazosin tamsulosin terazosin</p> <p><b><u>Non Preferred Agent (s)</u></b></p> <p>Cardura<sup>®</sup> Cardura XL<sup>®</sup> Flomax<sup>®</sup> Hytrin<sup>®</sup> Rapaflo<sup>™</sup> Uroxatral<sup>®</sup></p>

Description of Recommendation	Final Decision (s)
<p><b><u>5-Alpha Reductase (5AR) Inhibitors</u></b></p> <ol style="list-style-type: none"> <li>DMS to select preferred agent (s) based on economic evaluation; however, at least one single-entity agent should be preferred.</li> <li>Agents not selected as preferred will be considered non preferred and require PA.</li> <li>For any new chemical entity in the 5-Alpha Reductase Inhibitors class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b> finasteride</p> <p><b><u>Non Preferred Agent (s)</u></b> Avodart<sup>®</sup> Jalyn<sup>®</sup> Proscar<sup>®</sup></p>
<p><b><u>5-Alpha Reductase (5AR) Inhibitors Clinical Criteria</u></b></p> <p>5-Alpha Reductase (5AR) Inhibitors will be approved for a diagnosis of benign prostatic hyperplasia (BPH) via an ICD-9 override.</p>	<p>5-Alpha Reductase (5AR) Inhibitors will be approved for a diagnosis of benign prostatic hyperplasia (BPH) via an ICD-9 override.</p>
<p><b><u>Tadalafil (Cialis<sup>®</sup>) Clinical Criteria</u></b></p> <p>Tadalafil (Cialis<sup>®</sup>) will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both:</p> <ul style="list-style-type: none"> <li>An alpha blocker for one month; AND</li> <li>A 5-Alpha Reductase Inhibitor for four months.</li> </ul> <p>Cialis<sup>®</sup> should not be used in combination with an alpha blocker.</p>	<p>Tadalafil (Cialis<sup>®</sup>) will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both:</p> <ul style="list-style-type: none"> <li>An alpha blocker for one month; AND</li> <li>A 5-Alpha Reductase Inhibitor for four months.</li> </ul> <p>Cialis<sup>®</sup> should not be used in combination with an alpha blocker.</p>
<p><b><u>Bladder Relaxants</u></b></p> <ol style="list-style-type: none"> <li>DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred.</li> <li>Only patients who are unable to swallow or tolerate oral medications should be approved for non-oral formulations of agents in this class.</li> <li>Continue current quantity limits on all agents in this class.</li> <li>Agents not selected as preferred will be considered non preferred and require PA.</li> <li>For any new chemical entity in the Bladder Relaxants Class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b> oxybutynin Toviaz<sup>™</sup> VESicare<sup>®</sup></p> <p><b><u>Non Preferred Agent (s)</u></b> Detrol<sup>®</sup> Detrol<sup>®</sup> LA Ditropan<sup>®</sup> XL Enablex<sup>®</sup> flavoxate Gelnique<sup>™</sup> Myrbetriq<sup>™</sup> oxybutynin ER Oxytrol<sup>®</sup> Sanctura<sup>®</sup> Sanctura<sup>®</sup> XR tolterodine tolterodine ER trospium trospium ER</p>

<b>Description of Recommendation</b>	<b>Final Decision (s)</b>
<p><b><u>Oral Oncology Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a first-line recommendation by the NCCN for each cancer type should be preferred. Due to new data on the treatment of CML, both imatinib and EITHER dasatinib OR nilotinib should be preferred.</li> <li>2. Continue quantity limits based on FDA-approved maximum dose.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back.</li> <li>5. For any new chemical entity in the Oral Oncology Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p>The final PDL placement will be determined after a review of this class at the next P&amp;T meeting.</p>
<p><b><u>Vaginal Antibiotics</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least metronidazole should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Vaginal Antibiotics class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b>  Cleocin<sup>®</sup> Ovules  metronidazole vaginal 0.75% gel</p> <p><b><u>Non Preferred Agent (s)</u></b>  Cleocin<sup>®</sup> cream  clindamycin vaginal 2% cream  Clindesse<sup>®</sup>  Metrogel Vaginal<sup>®</sup>  Vandazole<sup>®</sup></p>
<p><b><u>Irritable Bowel Syndrome</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Irritable Bowel Syndrome class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b>  Amitiza<sup>®</sup>  Linzess<sup>®</sup></p> <p><b><u>Non Preferred Agent (s)</u></b>  Lotronex<sup>®</sup></p>

<b>Description of Recommendation</b>	<b>Final Decision (s)</b>
<p><b><u>Irritable Bowel Syndrome Clinical Criteria</u></b>  Agents will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Irritable Bowel Syndrome with constipation (linaclotide and lubiprostone) or with diarrhea (alosetron); OR</li> <li>• Chronic Idiopathic Constipation after failure of one laxative (linaclotide and lubiprostone); OR</li> <li>• Opioid-Induced Constipation (lubiprostone) if the following are true: <ul style="list-style-type: none"> <li>○ Patient is experiencing chronic, non-cancer pain; and</li> <li>○ Patient has tried and failed one laxative.</li> </ul> </li> </ul>	<p>Agents will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Irritable Bowel Syndrome with constipation (linaclotide and lubiprostone) or with diarrhea (alosetron); OR</li> <li>• Chronic Idiopathic Constipation after failure of one laxative (linaclotide and lubiprostone); OR</li> <li>• Opioid-Induced Constipation (lubiprostone) if the following are true: <ul style="list-style-type: none"> <li>○ Patient is experiencing chronic, non-cancer pain; and</li> <li>○ Patient has tried and failed one laxative.</li> </ul> </li> </ul>
<p><b><u>Topical Rosacea Agents</u></b></p> <ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require prior authorization.</li> <li>3. For any new chemical entity in the Topical Rosacea Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>	<p><b><u>Selected Preferred Agent (s)</u></b>  metronidazole lotion, cream, gel</p> <p><b><u>Non Preferred Agent (s)</u></b>  Azelex<sup>®</sup>  Finacea<sup>®</sup>  Finacea<sup>®</sup> Plus  MetroCream<sup>®</sup>  MetroGel<sup>®</sup>  MetroGel<sup>®</sup> Kit  MetroLotion<sup>®</sup>  Mirvaso<sup>®</sup>  Noritate<sup>®</sup>  Rosadan<sup>®</sup> Kit</p>

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<p><b>Palivizumab (Synagis<sup>®</sup>) Clinical Criteria</b></p> <p><b>Length of authorization:</b></p> <ul style="list-style-type: none"> <li>Authorization will be granted for a maximum of 5 doses during RSV season (five monthly doses of 15 mg/kg IM). Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.</li> <li>For infants and children &lt; 24 months of age, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).</li> </ul>	<p><b>Length of authorization:</b></p> <ul style="list-style-type: none"> <li>Authorization will be granted for a maximum of 5 doses during RSV season (five monthly doses of 15 mg/kg IM). Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.</li> <li>For infants and children &lt; 24 months of age, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).</li> </ul>																				
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<p>GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease, O<sub>2</sub>=oxygen; HD=heart disease; CHF=congestive heart failure, PH=pulmonary hypertension, CF=cystic fibrosis, ECMO=extracorporeal membrane oxygenation</p> <p>*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1<sup>st</sup> year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable</p>	<p>GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease, O<sub>2</sub>=oxygen; HD=heart disease; CHF=congestive heart failure, PH=pulmonary hypertension, CF=cystic fibrosis, ECMO=extracorporeal membrane oxygenation</p> <p>*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1<sup>st</sup> year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable</p>																				

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<p><b>Botulinum Toxins Clinical Criteria</b>  AbobotulinumtoxinA (Dysport™) OR rimabotulinumtoxinB (Myobloc®) will be approved for a diagnosis of cervical dystonia.</p> <p>IncobotulinumtoxinA (Xeomin®) will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Cervical dystonia; OR</li> <li>• Blepharospasm after trial and failure of onabotulinumtoxinA (Botox®).</li> </ul> <p>OnabotulinumtoxinA (Botox®) will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Blepharospasm ; OR</li> <li>• Cervical dystonia; OR</li> <li>• Severe primary axillary hyperhidrosis ; OR</li> <li>• Strabismus; OR</li> <li>• Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: <ul style="list-style-type: none"> <li>○ Muscle relaxants; or</li> <li>○ Bracing; or</li> <li>○ Splinting; or</li> <li>○ Occupational therapy; or</li> <li>○ Physical therapy; OR</li> </ul> </li> <li>• Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): <ul style="list-style-type: none"> <li>○ Prophylactic therapy with at least two (2) of the following: <ul style="list-style-type: none"> <li>▪ Beta-blocker; or</li> <li>▪ Amitriptyline; or</li> <li>▪ Valproate; or</li> <li>▪ Topiramate; AND</li> </ul> </li> <li>○ Tried and failed abortive therapy with two triptans; OR</li> </ul> </li> <li>• Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication; OR</li> <li>• Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency after trial and failure of or contraindication to an anticholinergic medication.</li> </ul>	<p>AbobotulinumtoxinA (Dysport™) OR rimabotulinumtoxinB (Myobloc®) will be approved for a diagnosis of cervical dystonia.</p> <p>IncobotulinumtoxinA (Xeomin®) will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Cervical dystonia; OR</li> <li>• Blepharospasm after trial and failure of onabotulinumtoxinA (Botox®).</li> </ul> <p>OnabotulinumtoxinA (Botox®) will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Blepharospasm ; OR</li> <li>• Cervical dystonia; OR</li> <li>• Severe primary axillary hyperhidrosis ; OR</li> <li>• Strabismus; OR</li> <li>• Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: <ul style="list-style-type: none"> <li>○ Muscle relaxants; or</li> <li>○ Bracing; or</li> <li>○ Splinting; or</li> <li>○ Occupational therapy; or</li> <li>○ Physical therapy; OR</li> </ul> </li> <li>• Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): <ul style="list-style-type: none"> <li>○ Prophylactic therapy with at least two (2) of the following: <ul style="list-style-type: none"> <li>▪ Beta-blocker; or</li> <li>▪ Amitriptyline; or</li> <li>▪ Valproate; or</li> <li>▪ Topiramate; AND</li> </ul> </li> <li>○ Tried and failed abortive therapy with two triptans; OR</li> </ul> </li> <li>• Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication; OR</li> <li>• Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency after trial and failure of or contraindication to an anticholinergic medication.</li> </ul>

Description of Recommendation	Final Decision (s)
<p><b><u>Clonidine Patch Clinical Criteria</u></b> Clonidine patches will be approved if any one of the following is true:</p> <ul style="list-style-type: none"> <li>• Patient is &lt;15 years old; OR</li> <li>• Patient cannot tolerate/absorb PO.</li> </ul>	<p>Clonidine patches will be approved if any one of the following is true:</p> <ul style="list-style-type: none"> <li>• Patient is &lt;15 years old; OR</li> <li>• Patient cannot tolerate/absorb PO.</li> </ul>
<p><b><u>Phenoxybenzamine (Dibenzyl<sup>®</sup>)</u></b> Phenoxybenzamine (Dibenzyl<sup>®</sup>) will be approved for a diagnosis of Pheochromocytoma only.</p>	<p>Phenoxybenzamine (Dibenzyl<sup>®</sup>) will be approved for a diagnosis of Pheochromocytoma only.</p>
<p><b><u>Lidocaine Patch (Lidoderm<sup>®</sup>) Clinical Criteria</u></b> Lidocaine patches (Lidoderm<sup>®</sup>) will be approved if any one of the following criteria is met:</p> <ul style="list-style-type: none"> <li>• Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR</li> <li>• Diagnosis of neuropathic pain and history of one agent in any of the following medication classes in the past 90 days: <ul style="list-style-type: none"> <li>○ Tricyclic antidepressant; or</li> <li>○ Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); or</li> <li>○ SNRI.</li> </ul> </li> </ul>	<p>Lidocaine patches (Lidoderm<sup>®</sup>) will be approved if any one of the following criteria is met:</p> <ul style="list-style-type: none"> <li>• Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR</li> <li>• Diagnosis of neuropathic pain and history of one agent in any of the following medication classes in the past 90 days: <ul style="list-style-type: none"> <li>○ Tricyclic antidepressant; or</li> <li>○ Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); or</li> <li>○ SNRI.</li> </ul> </li> </ul>
<p><b><u>Capsaicin Patch (Qutenza<sup>®</sup>) Clinical Criteria</u></b> Capsaicin Patch (Qutenza<sup>®</sup>) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents:</p> <ul style="list-style-type: none"> <li>• Tricyclic antidepressant; OR</li> <li>• Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); OR</li> <li>• SNRI.</li> </ul>	<p>Capsaicin Patch (Qutenza<sup>®</sup>) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents:</p> <ul style="list-style-type: none"> <li>• Tricyclic antidepressant; OR</li> <li>• Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); OR</li> <li>• SNRI.</li> </ul>
<p><b><u>Prenatal Vitamins Clinical Criteria</u></b> Prenatal vitamins will be approved if one of the following is true:</p> <ul style="list-style-type: none"> <li>• Patient is female and currently pregnant; OR</li> <li>• Patient is female and actively nursing; OR</li> <li>• Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.</li> </ul>	<p>Prenatal vitamins will be approved if one of the following is true:</p> <ul style="list-style-type: none"> <li>• Patient is female and currently pregnant; OR</li> <li>• Patient is female and actively nursing; OR</li> <li>• Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.</li> </ul>
<p><b><u>Becaplermin (Regranex<sup>®</sup>) Clinical Criteria</u></b> Becaplermin (Regranex<sup>®</sup>) will be approved for a diagnosis of lower extremity diabetic neuropathic ulcers.</p>	<p>Becaplermin (Regranex<sup>®</sup>) will be approved for a diagnosis of lower extremity diabetic neuropathic ulcers.</p>
<p><b><u>Peginterferon Alfa 2b (Sylatron<sup>™</sup>) Clinical Criteria</u></b> Peginterferon Alfa 2b (Sylatron<sup>™</sup>) will be approved for a diagnosis of melanoma only.</p>	<p>Peginterferon Alfa 2b (Sylatron<sup>™</sup>) will be approved for a diagnosis of melanoma only.</p>

Description of Recommendation	Final Decision (s)
<p><b>Omalizumab (Xolair®) Clinical Criteria</b></p> <p>Initial Therapy (6 months):  Xolair® (omalizumab) will be approved for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Moderate to severe asthma (step 5 or higher) if ALL of the following are true: <ul style="list-style-type: none"> <li>○ 12 years of age or older; AND</li> <li>○ Positive skin test or in vitro reactivity to a perennial aeroallergen; AND</li> <li>○ FEV1 of &lt;80% while on asthma controller medication; AND</li> <li>○ Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled beta2-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial.</li> </ul> </li> <li>• Chronic idiopathic urticaria if ALL of the following are true: <ul style="list-style-type: none"> <li>○ 12 years of age or older; AND</li> <li>○ The underlying cause of the patient's condition has been ruled out and is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; AND</li> <li>○ Documented baseline urticaria activity score (UAS7), renewals will require submission of current UAS7 (within previous 30 days); AND</li> <li>○ One of the following: <ul style="list-style-type: none"> <li>▪ 3-month trial and failure of two (2) H1 antihistamines at maximally tolerated doses and patient has documented ongoing symptoms of chronic idiopathic urticaria; or</li> <li>▪ 3-month trial and failure of one antihistamine products and one (1) of the following leukotriene antagonists: Singulair (montelukast) OR Accolate (zafirlukast) and patient has documented ongoing symptoms of chronic idiopathic urticaria.</li> </ul> </li> </ul> </li> </ul> <p>Continuation of Therapy:  Xolair® (omalizumab) will be approved for continuation of therapy for the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Moderate to severe asthma (step 5 or higher) if one</li> </ul>	<p>The final criteria will be determined after a review of this product at the next P&amp;T meeting.</p>

of the following is true:

- During previous treatment with Xolair<sup>®</sup>, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair<sup>®</sup> baseline, OR
- The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair<sup>®</sup> and the patient has been able to reduce their oral corticosteroid dose to less than their pre-Xolair<sup>®</sup> baseline or to  $\leq 5$  mg daily, OR
- The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of Xolair<sup>®</sup> and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-Xolair<sup>®</sup> baseline.
- Chronic idiopathic urticaria if ALL of the following are true:
  - Treatment with Xolair<sup>®</sup> (omalizumab) has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; AND
  - Submitted current UAS7 was recorded within the past 30 days.