LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
CORE PHARMACY & THERAPEUTICS COMMITTEE

September 15th, 2015

TO: DHS Chief Medical Officers
DHS Facility Pharmacy Directors

FROM: Amy Gutierrez, Pharm.D.
Jeffrey Guterman, M.D.
Chairs, DHS Core Pharmacy and Therapeutics Committee

RE: September 2015 DHS Core Formulary Decisions

DHS CORE FORMULARY

Restriction Change

Drug Product	Comments
Dexmedetomidine (Precedex®) injection	Restricted to Adult ICU ventilated patients that meet all hospital-defined ICU extubation weaning criteria (except for agitation) and with anticipated extubation within 24 hours. Restricted to PICU ventilated patients administered high dose midazolam and fentanyl for sedation with anticipated extubation within 24 hours. Dexmedetomidine Prior Authorization form required. ***(see attached revised form)***
Emtricitabine/Tenofovir (Truvada®) oral tablets	Restricted to Infectious Disease and HIV Services/Clinic for the treatment of HIV, HIV pre-exposure prophylaxis per CDC guidelines***, OR HIV post-exposure prophylaxis per CDC guidelines.***
Etanercept (Enbrel®) subcutaneous syringe	Restricted to Rheumatology ***for patients who have failed/intolerant to adalimumab, or continuation of therapy for stabilized patients. RA patients deemed appropriate for biologic therapy should be initiated on adalimumab.*** Restricted to Dermatology for patients that meet ALL of the following criteria: 1) Plaque psoriasis present >6 months 2) >10% of body surface area affected 3) Documented failure/intolerance to topical and conventional therapy.
Fosfomycin (Monurol®) oral packet	***Restricted to Fosfomycin Prior Authorization Form (see attached revised form).***
Raltegravir (Isentress®) oral tablets	Restricted to Infectious Disease and HIV Services/Clinic for the treatment of HIV, ***OR HIV post-exposure prophylaxis per CDC guidelines.***

***Note: All formulary dosage strengths are included unless otherwise specified.*
Bolded and italicized comments denote restriction change.

Dosage Form Addition

Drug Product	Comments	CDM Code*
Tocilizumab (Actemra®) subcutaneous syringe	Restricted to Rheumatology as a second-line agent for patients who failed at least 1 TNF- Inhibitor. Tocilizumab Prior Authorization Form required. (see attached revised form)	**83088600**

**Chargemaster drug code (for pharmacy use).*

Formulary Requests Not Approved

Drug Product	Comments
Timothy Grass (Grastek®) sublingual tablet	Alternatives available on the DHS Core Formulary.
Tofacitinib (Xeljanz®) oral tablet	Alternatives available on the DHS Core Formulary.

***Note: All formulary dosage strengths are included unless otherwise specified.*

MY HEALTH LA FORMULARY

New Drug Addition

Drug Product	Comments
Emtricitabine/Tenofovir (Truvada®) oral tablets	Restricted to Infectious Disease and HIV Services/Clinic for the treatment of HIV, HIV pre-exposure prophylaxis per CDC guidelines, OR HIV post-exposure prophylaxis per CDC guidelines. Patient Assistance Program available.
Raltegravir (Isentress®) oral tablets	Restricted to Infectious Disease and HIV Services/Clinic for the treatment of HIV, OR HIV post-exposure prophylaxis per CDC guidelines. Patient Assistance Program available.

DHS Core P&T Approved Attachments:

- DHS Dexmedetomidine (Precedex®) Prior Authorization form (*revised, attached*)
- DHS Fosfomycin (Monurol®) Prior Authorization form (*revised, attached*)
- DHS Tocilizumab (Actemra®) Prior Authorization form (*revised, attached*)

Dexmedetomidine (Precedex®) Prior-Authorization Form

FOR ADULT USE ONLY (18 year of age and greater than 40 kg weight)

Health Services
LOS ANGELES COUNTY

Prescriber Instructions: Please check ALL APPROPRIATE BOXES and complete form thoroughly. Incomplete form will NOT be reviewed and may affect authorization approval.

Check One:	☐ **LAC+USC**	☐ **HUMC**	☐ **OVMC**	☐ **RLA**

FORMULARY RESTRICTION

Restricted to Adult ICU ventilated patients that meet all hospital-defined ICU extubation weaning criteria (except for agitation) and with anticipated extubation within 24 hours. Maximum use of 24 hours per authorization.
ICU attending may renew additional 24 hour authorization upon discussion with pharmacist (no additional form needed).

APPROVAL CRITERIA: Please complete boxes below for a patient selected for dexmedetomidine therapy. Both must be met prior to approval for use of dexmedetomidine

YES	**All criteria must be met for authorization**
☐	ICU attending approval by: _____ Date: _____Time: _____
☐	Patient has met hospital-defined ICU extubation weaning criteria (except for agitation) and will be extubated within the next 24 hours

Caution should be exercised when utilizing dexmedetomidine with patients with advanced heart block, baseline bradycardia, severe ventricular dysfunction, hepatic/renal impairment, or in the elderly.

Approved DEXMEDETOMIDINE DOSING GUIDELINES

Continuous Infusion: 0.2-1.4mcg/kg/hr

Duration of Therapy: *Pharmacy will dispense 12-hour supply at one time. May be repeated X 1 for maximum of 24-hour dose per authorization. ICU attending may renew 24 hour authorization.*

Additional Comments (e.g., initial rate, titration parameters):

Prescriber Name (Printed): _____ **Prescriber Signature:**_____

Prescriber ID #: _____ **Telephone #:** _____ **Pager #:**_____ **Date:**_____

PHARMACY USE ONLY	
Authorization Status:	
☐ **Approved**	☐ **Denied**
Date Received:	Date of Decision:
Pharmacist Reviewer:	

Patient Name:

MRUN #:

DOB:

Fosfomycin (Monurol®) Prior Authorization Form

Health Services
LOS ANGELES COUNTY

Instructions

1. Please complete all sections of the form. Incomplete forms will be returned to the prescriber.
2. Submit form along with the prescription order to the facility pharmacy. This form is not a substitute for a prescription order. Any form submitted without a prescription order will be considered incomplete and not reviewed.
3. Additional forwarding to DHS Pharmacy Affairs for processing is required prior to OUTPATIENT dispensing. Please see "Formulary Advisor" on Micromedex for details; local DHS pharmacy will facilitate.
4. Inpatient/Clinic use: CMO or designee approval is not needed for cases where the criteria are met. If all criteria below are not met, form will be forwarded by the facility pharmacy to DHS Pharmacy Affairs for review. The CMO or designee will provide final decision in these cases.
5. For Outpatient dispensing: Local facility pharmacy will forward form to DHS Pharmacy Affairs. CMO or designee will provide final decision for uninsured patients that do not meet criteria. Respective health plans will provide final decision for insured patients.

Notes

1. This PA form must be submitted for all written inpatient and outpatient prescriptions.
2. Authorizations are limited to **single course** therapy. Additional authorization is required for any use after the initial course of therapy period.
3. Please complete **ALL** areas below, as incomplete prior authorization requests **MAY AFFECT THE OUTCOME** of this request.

STEP 1: EXCLUSION CRITERIA (*If any of the following criteria apply, the patient does **NOT** qualify for fosfomycin use*)	
Patient has known hypersensitivity to fosfomycin (Monurol®)	
STEP 2: APPROVAL CRITERIA (*Check **ALL** criteria that apply, **ALL** lines must be checked for approval. **None** of the exclusion criteria above apply.)* **Note:** Any incomplete information **MAY AFFECT THE OUTCOME** of this request.	
☐	Symptomatic UTI requiring antibiotic treatment
☐	Available results of urine analysis (UA) supporting the diagnosis of above
☐	Urine culture (<3 weeks old) demonstrating an organism sensitive to **FOSFOMYCIN**
☐	Urine culture (<3 weeks old) showing sensitivity to **NO** other oral antimicrobial appropriate for use
STEP 3: DOSAGE (*Check the appropriate dosage*)	
☐	Uncomplicated UTI: 3gm orally single dose
☐	Complicated UTI – CrCl ≥ 50 mL/min: 3gm orally every 48 hours
☐	Complicated UTI – CrCl < 50 mL/min: 3gm orally every 72 hours
STEP 4: ADDITIONAL EXPLANATION *(For additional comments, please attach to form)*	

STEP 5: PRESCRIBER INFORMATION		
Prescriber Name (Printed):		Prescriber Signature: Date: _____ *I declare that the information on this form, to my best knowledge and belief, is true, correct, and complete.*
Prescriber NPI #:	Clinic/Ward:	
Direct Telephone/Pager #:	Email:	

STEP 6: ATTACH TO ORIGINAL PRESCRIPTION	
Pharmacy Review: Approval criteria met? ☐ **YES** ☐ **NO** See instructions at top of form for next step following review.	
Date Received:	Date of Decision:
Pharmacist Reviewer:	
Medical Review: ☐ **Approved** ☐ **Denied**	
Date Received:	Date of Decision:
CMO or Designee:	

Falagas ME, Vouloumanou EK, Togias AG, *et al*. Fosfomycin versus other antibiotics for the treatment of cystitis: a meta-analysis of randomized controlled trials. Journal of Antimicrobial Chemotherapy 2010; 65: 1862-1877.

Falagas ME, Kastoris AC, Kapaskelis AM, *et al*. Fosfomycin for the treatment of multidrug-resistant, including extended-spectrum beta-lactamase producing, Enterobacteriaceae infections: a systematic review. *Lancet Infectious Disease* 2010; 10: 43-50

Tocilizumab (Actemra®) Prior Authorization Form

Health Services
LOS ANGELES COUNTY

Instructions

1. Please complete all sections of the form. Incomplete forms will be returned to the prescriber.
2. Submit form along with the prescription order to the facility pharmacy. This form is not a substitute for a prescription order. Any form submitted without a prescription order will be considered incomplete and not reviewed.
3. Additional forwarding to DHS Pharmacy Affairs for processing is required prior to OUTPATIENT dispensing. Please see "Formulary Advisor" on Micromedex for details; local DHS pharmacy will facilitate.
4. Inpatient/Clinic use: CMO or designee approval is not needed for cases where the criteria are met. If all criteria below are not met, form will be forwarded by the facility pharmacy to DHS Pharmacy Affairs for review. The CMO or designee will provide final decision in these cases.
5. For Outpatient dispensing: Local facility pharmacy will forward form to DHS Pharmacy Affairs. CMO or designee will provide final decision for uninsured patients that do not meet criteria. Respective health plans will provide final decision for insured patients.

Notes

1. This form must be completed by the Rheumatology Service.
2. This prior authorization form must be submitted for all written inpatient and outpatient prescriptions.
3. Authorizations are limited to a maximum of **six (6) months** of therapy. Additional authorization is required for any use after this initial 6-month period.
4. Please complete **ALL** areas below, as incomplete prior authorization requests **MAY AFFECT THE OUTCOME** of this request.

STEP 1: EXCLUSION CRITERIA *(If any of the following criteria apply, the patient does **NOT** qualify for tocilizumab use)*	
Patient on concurrent therapy with another biologic DMARD	Baseline platelet count < 100,000/mm^3
Patient has a localized or active systemic infection	Baseline ALT and/or AST > 1.5x the upper limit of normal (ULN)
Patient has active hepatic disease or hepatic impairment	Patient has known hypersensitivity to tocilizumab (Actemra®)
Baseline Absolute Neutrophil Count (ANC) < 2000/mm^3	
☐ Patient does not possess **ANY** exclusion criteria identified above.	

STEP 2: APPROVAL CRITERIA *(Check **ALL** criteria that apply, **ALL** lines must be checked for approval)* **Note:** Any incomplete information **MAY AFFECT THE OUTCOME** of this request.	
☐	Diagnosis of Rheumatoid Arthritis as defined by ACR Classification Criteria
☐	Moderate to severe, active disease as defined by DAS-28, CDAI or SDAI
☐	Patient has failed at least one TNF-alpha inhibitor therapy due to inadequate disease control or intolerance

STEP 3: DOSAGE *(Check the appropriate dosage)*	
☐ 162 mg subcutaneously every other week (every week dosing if ≥ 100kg)	☐ 4 mg/kg intravenously every 4 weeks (may increase to 8mg/kg based on clinical response, maximum 800mg per infusion)
	☐ Other _____ *(Specify dose and frequency: explain below)*

STEP 4: ADDITIONAL EXPLANATION *(For additional comments, please attach to form)*

STEP 5: PRESCRIBER INFORMATION

Prescriber Name (Printed):		Prescriber Signature:
Prescriber NPI #:	Clinic/Ward: ☐ Rheumatology	Date: _____
Direct Telephone/Pager #:	Email:	*I declare that the information on this form, to my best knowledge and belief, is true, correct, and complete.*

STEP 6: ATTACH TO ORIGINAL PRESCRIPTION

Pharmacy Review: Approval criteria met? ☐ **YES** ☐ **NO** If not met, submit to CMO or designee.	
Date Received:	Date of Decision:
Pharmacist Reviewer:	
Medical Review: ☐ **Approved** ☐ **Denied**	
Date Received:	Date of Decision:
CMO or Designee:	

Cohen SB, Emery P, Greenwald MW, *et al.* Rituximab for rheumatoid arthritis refractory to anti-tumor necrosis factor therapy. REFLEX study.
Genovese MC, Becker JC, Schiff M, *et al*. Abatacept for rheumatoid arthritis refractory to tumor necrosis factor A inhibition. ATTAIN study.
Emery P, Keystone E, Tony HP, *et al*. IL-6 Receptor Inhibition with Tocilizumab Improves Treatment Outcomes in Patients with Rheumatoid Arthritis Refractory to Anti-Tumor Necrosis Factor Biologicals. RADIATE study.

LA County DHS P&T Committee Approved: 11/11, Revised 1/12, 9/15