Bobby Jindal
GOVERNOR

Kathy H. Kliebert
SECRETARY

State of Louisiana

Department of Health and Hospitals
Bureau of Health Services Financing

MEMORANDUM

DATE: March 31, 2015

TO: All Louisiana Medicaid Providers

FROM: J. Ruth Kennedy, Medicaid Director

SUBJECT: Clinical Pre-Authorization for Androgenic Agents, Ivacaftor (Kalydeco®), and Roflumilast (Daliresp®) for La. Medicaid Pharmacy Program

Effective April 8, 2015, the Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana Medicaid Drug Utilization Review (DUR) Board has established clinical pre-authorization criteria for Androgenic Agents (testosterone and methyltestosterone containing products, excluding oxandrolone), Ivacaftor (Kalydeco®), and Roflumilast (Daliresp®).

Claims for Androgenic Agents (testosterone and methyltestosterone containing products, excluding oxandrolone), Ivacaftor (Kalydeco®), and Roflumilast (Daliresp®) will be reimbursed at Point of Sale (POS) when the prescriber has obtained an approved clinical pre-authorization and POS requirements are met. Prescribers must complete the *Clinical Pre-Authorization Form* in full and fax to 866-797-2329. The criteria and form are included with this memo. Refer to www.lamedicaid.com.

Pharmacy claims for Androgenic Agents (excluding oxandrolone), Ivacaftor (Kalydeco®), or Roflumilast (Daliresp®) without clinical pre-authorization will deny at POS with:

NCPDP reject code 88 (DUR Reject Error) mapped to
EOB code 066 (Clinical Pre-Authorization Required)

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

If you have questions about the contents of this memo, you may contact the Pharmacy Help Desk at 800-437-9101 or refer to www.lamedicaid.com.

MCJ/MBW/ESF

c: Bayou Health Plans
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Magellan of Louisiana (Managed Care)
Melwyn B. Wendt
Molina

Clinical Pre-Authorization Criteria for Daliresp® (roflumilast)

Requests for roflumilast will be considered for approval if all of the following criteria are met:

1. Recipient must be 18 years of age or older on date of request; AND

2. Recipient has a documented diagnosis of severe COPD associated with chronic bronchitis and a history of exacerbations; Documentation must include, but is not limited to:
    a. Results and date of last FEV1 (Severe/Very Severe COPD: FEV1 < 50% predicted); AND
    b. A record of a history of COPD exacerbations, including dates of exacerbations; AND
    c. Evidence that patient is receiving standard treatment for COPD (e.g. long-acting bronchodilator, beta agonist, and/or anticholinergic medications); AND

3. Recipient does not have a documented contraindication to roflumilast. Roflumilast is contraindicated in the setting of moderate to severe liver impairment (Child-Pugh B or C). Recipient will not be concomitantly receiving a contraindicated or 'not recommended' medication while on roflumilast. See prescribing information for a list of drug interactions.

Clinical Pre- Authorization Criteria for Kalydeco® (ivacaftor)

Requests for ivacaftor will be considered for approval if all of the following criteria are met:

1. Recipient is 2 years or older on date of request with a documented diagnosis of cystic fibrosis; AND

2. Recipient has one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene : G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R ; AND

3. Recipient is not homozygous for the F508del mutation in the CFTR gene; AND

4. Recipient does not have a documented contraindication, including contraindicated medication, to ivacaftor. See prescribing information for a list of drug interactions.

Clinical Pre-Authorization Criteria for Androgenic Agents (Therapeutic Class F1A, excluding oxandrolone)

Requests for androgenic agents will be considered for approval if all applicable criteria are met:

1. Requests must include patient-specific documentation of FDA-approved indications AND for hypogonadism in adult males an associated medical condition must be included with requests. Indications and medical conditions are limited to specific agents as summarized in Tables 1-3.

   A. Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.

   B. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

   C. Delayed puberty in males: to induce pubertal changes in hypogonadal males

   D. In women as secondary treatment with advancing inoperable metastatic (skeletal) breast cancer who are 1 to 5 years postmenopausal. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor.

2. <u>All</u> initial requests must include baseline hematocrit levels. Hematocrit levels should be reevaluated at 3 to 6 months and then annually, if therapy continues for that duration.

   Approval Criteria: Less than or equal to 54%

3. Initial requests for use in <u>hypogonadism</u> must also include laboratory documentation for 2 serum testosterone levels drawn between 8:00 AM and 10:00 AM obtained on different days.

   Approval Criteria: Less than 300 ng/dL on both days **OR** below the lower limit of normal on both days for the individual reporting laboratory (must provide documentation of normal limits for individual reporting laboratory)

4. Initial requests for use in <u>delayed puberty in males</u> must also contain radiographic results of baseline x-rays of hand and wrist. These x-rays, necessary to determine the effect of testosterone treatment on epiphyseal centers. Follow-up x-rays must be repeated every 6 months, if therapy is required for that duration.

5. Initial request for use in <u>breast cancer</u> must also contain results of urine and/or serum total calcium levels as described in the prescribing information for each drug. Urine and/or serum total calcium levels must monitored at least every 6 months.

   Approval Criteria: Less than 10.3 mg/dL (corrected for albumin)
   *Corrected Calcium = (0.8 * (Normal Albumin - Pt's Albumin)) + Serum Ca*

6. All requests must conform to age limitation as defined in the prescribing information for each agent.

Table 1. FDA Indications and Associated Medical Conditions for Topical, Transdermal, Buccal, and Nasal Testosterone Agents

	Androgel	Fortesta	Testim	Testosterone Gel	Vogelxo	Axiron	Androderm	Striant	Natesto
	Topical Gel					Top Soln	TD	Buccal	Nasal Gel
Primary Hypogonadism (congenital or acquired)*	x	x	x	x	x	x	x	x	x
Hypogonadotropic Hypogonadism (congenital or acquired)**	x	x	x	x	x	x	x	x	x
Delayed Puberty in Males	NA	NA	NA	NA	NA	NA	NA	NA	NA
Inoperable Female Metastatic Breast Cancer	NA	NA	NA	NA	NA	NA	NA	NA	NA

* Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

** Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.

NA=Not an FDA approved indication

Table 2. FDA Indications and Associated Medical Conditions for Injectable Testosterone Agents

	Testopel	Testosterone cypionate	Testosterone enanthate	Testosterone undecanoate
	SQ Implant	Injection		
Primary Hypogonadism (congenital or acquired)				
(a) cryptorchidism	x	x	x	x
(b) bilateral torsion	x	x	x	x
(c) orchitis	x	x	x	x
(d) vanishing testis syndrome	x	x	x	x
(e) orchiectomy	x	x	x	x
(f) Klinefelter's Syndrome	NA	NA	NA	x
(g) chemotherapy	NA	NA	NA	x
(h) toxic damage from alcohol or heavy metals	NA	NA	NA	x
Hypogonadotropic Hypogonadism (congenital or acquired)				
(a) idiopathic gonadotropin or LHRH deficiency	x	x	x	x
(b) pituitary-hypothalamic injury from trauma, tumors, or radiation	x	x	x	x
Delayed Puberty in Males	x	NA	x	NA
Inoperable Female Metastatic (Skeletal) Breast Cancer	NA	NA	x	NA

NA= Not an FDA approved indication

Table 3. FDA Indications and Associated Medical Conditions for Oral Testosterone Agents

	Fluoxymesterone	Methyltestosterone
Primary Hypogonadism (congenital or acquired)		
(a) cryptorchidism	x	x
(b) bilateral torsion	x	x
(c) orchitis	x	x
(d) vanishing testis syndrome	x	x
(e) orchiectomy	x	x
(f) Klinefelter's Syndrome	NA	NA
(g) chemotherapy	NA	NA
(h) toxic damage from alcohol or heavy metals	NA	NA
Hypogonadotropic Hypogonadism (congenital or acquired)		
(a) idiopathic gonadotropin or LHRH deficiency	x	x
(b) pituitary-hypothalamic injury from trauma, tumors, or radiation	x	x
Delayed Puberty in Males	x	x
Inoperable Female Metastatic (Skeletal) Breast Cancer	x	x

NA=Not an FDA approved indication

Louisiana Medicaid
Pharmacy Clinical Pre-Authorization Form

Fax or Mail this form to:
1-866-797-2329
La Medicaid RxPA Operations
ULM School of Pharmacy
1800 Bienville Drive
Monroe, LA 71201-3765

Revised Date: 2/12/2015

MEMBER INFORMATION

Patient Name: Last Name	First Name	MI	
Date of Birth:	**Sex:** ☐ Male ☐ Female	**Height:**	**Weight:**
Address:	City	State	Zip Code
Phone #:	**Medicaid Recipient ID#: (required)**	**Plan Policy ID#: (optional)**	

PRESCRIBING PRACTITIONER INFORMATION

Practice Name:	**Specialty:**	**NPI # (2):**	
Prescribing Practitioner Name:	**Medicaid Provider ID #: (required)**	**NPI # (1):**	**DEA/License #:**
Address:	City	State	Zip Code
Phone #:	**Fax #:**	**Office Contact:**	**EPSDT Support Coordinator (Name / Address): (optional)**

MEDICATION INFORMATION

Drug Name:		**Dosage Form:**	**Quantity:**
Strength:	**Directions:**		
Dispense as Written: ☐ Yes ☐ No	**Substitutes Permitted:** ☐ Yes ☐ No	**Number of Refills:**	
Currently on This Medication: ☐ Yes ☐ No	**Other Medications Tried toTreat This Condition:**	**Dates:**	
List Other Current Medications: ☐ *See attached list*			
Reasons for Discontinuation of Tried Therapies:			
Diagnosis/Indication:		**ICD Diagnosis Code:**	
Rationale and/or Other Information Relevant (☐ *included* lab results) to the Review of This Authorization Request:			
Drug Allergies:			

PHARMACY INFORMATION (Optional)

Pharmacy Name:	**Phone #:**	**Fax #:**

Prescribing Practitioner Signature: _____ **Date:** _____

For more information, refer to www.lamedicaid.com and follow the "Pharmacy and Prescribing Providers" link.