Alabama Medicaid Agency

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Governor

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STEPHANIE MCGEE AZAR
Commissioner

March 20, 2017

Dear Pharmaceutical Manufacturer:

This correspondence is to provide you with formal written notification of an upcoming meeting of the Alabama Medicaid Pharmacy & Therapeutics (P&T) Committee, to be held on **Wednesday, May 10, 2017**. This meeting may involve review of one or more of your company's drug products. Please note: this meeting will be held in the Commissioner's Board Room at the Alabama Medicaid Building located in Montgomery, Alabama and will begin at 9:00 a.m. All meetings of this Committee are open to the public.

The following is a list of drug classes for review at this meeting:

Drug Class RE-REVIEWS	
1. First Generation Antihistamines a. Ethanolamine Derivatives-AHFS 040404 b. Ethylenediamine Derivatives-AHFS 040408 c. Propylamine Derivatives-AHFS 040420 2. Estrogens-AHFS 681604 3. Alpha Glucosidase Inhibitors-AHFS 682002 4. Amylinomimetics-AHFS 682003 5. Biguanides-AHFS 682004 6. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors-AHFS 682005	7. Incretin Mimetics-AHFS 682006 8. Insulins-AHFS 682008 9. Meglitinides-AHFS 682016 10. Sodium-glucose Cotransport 1 Inhibitors-AHFS 682017 11. Sodium-glucose Cotransport 2 Inhibitors-AHFS 682018 12. Sulfonylureas-AHFS 682020 13. Thiazolidinediones-AHFS 682028 14. Antidiabetic Agents, Miscellaneous-AHFS 682092 15. Multivitamin Preparations: Prenatal Vitamins-AHFS 882800

Drug Class Initial Review
1. Immunomodulatory Agents used to treat Multiple Sclerosis-AHFS 922000 [Agents included: Zinbryta® (daclizumab), Tecfidera® (dimethyl fumarate), Gilenya® (fingolimod), Copaxone® (glatiramer acetate), Glatopa® (glatiramer acetate), Avonex® (interferon beta 1a), Rebif® (interferon beta 1a), Betaseron® (interferon beta 1b), Extavia® (interferon beta 1b), Tysabri® (natalizumab), Plegridy® (peginterferon beta-1a), Aubagio® (teriflunomide)]

New Drug Reviews
1. Dyanavel XR® (Amphetamines)-AHFS 282004

Effective for July 1, 2016 PDL Updates: Rule No. 560-X-16-.27 […] *Medicaid may, to the extent permitted under 42 U.S.C. §1396r-8(d), enter into an agreement with a manufacturer to designate a drug that is subject to prior authorization as a preferred drug.*

While we understand there is a level of coordination between members of the manufacturing industry and a provider through the normal course of business, Alabama Medicaid asks manufacturers to respect P&T Committee members' commitment to the State of Alabama by following the procedures available through the P&T policy. Also, as outlined in the P&T Committee Statement of Integrity, Committee members agree not to have ex parte contacts or discussions with manufacturers or representatives whose drugs are presented for review. This is specifically regarding drugs to be reviewed in an upcoming Medicaid P&T meeting.

As you may be aware, manufacturers whose products are scheduled for review are allowed the opportunity to provide written clinical comments for distribution to the Medicaid P&T Committee members prior to the meeting. For products slated for P&T Committee review, manufacturers are also allowed the opportunity to make brief (no more than 5 minutes) oral summary presentations of their products' clinical data to the Medicaid P&T Committee on the day of the meeting. At the initiation of the 5 minute presentation, the speaker will be required to state any financial interest in or other relationship with the manufacturer of any product(s) the speaker intends to discuss. Speakers may not solicit questions from P&T members during the oral presentation. All questions from Medicaid P&T Committee members regarding specific products and/or AHFS drug classes will be addressed by the clinical contractor or Medicaid after the clinical review of the class.

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Approval for distribution of written clinical comments to P&T Committee members and approval of oral presentation summary submissions are based strictly upon the following guidelines:

Written Comments:

1) All written comments must be e-mailed to Medicaid's Clinical Contractor, University of Massachusetts Medical School Clinical Pharmacy Services (UMass Clinical Pharmacy Services) at clinical.contractor@umassmed.edu and received no later than **Wednesday, April 19, 2017**. Submissions must include the full contact information (mailing address, phone, fax, and e-mail) of the designated manufacturer's point of contact.
2) Written comments should be submitted in PDF format and should be limited to one drug product per PDF file. Manufacturers wishing to provide written comments on more than one drug product must submit a separate PDF file for each product.
3) **Submissions are limited to 100 pages 12 font for each drug product. Submissions must be clearly labeled as "Written Comments" on the first page of the file.**
4) **Submissions file names must be clearly labeled as "Written Comments".**
5) Written comments should be limited to peer reviewed published clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information. Posters, podium presentations and other such information will not be accepted.**
6) Written comments must be limited to sound clinical evidence and to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content.

Oral Presentation Summaries:

1) Written notification of your intent to make an oral presentation must be e-mailed to UMass Clinical Pharmacy Services at clinical.contractor@umassmed.edu and received no later than **Wednesday, April 19, 2017**. Submissions must include the full contact information (mailing address, phone, fax, and e-mail) of the designated manufacturer's point of contact.
2) Oral presentation summaries should be submitted in PDF format and should be limited to one drug product per PDF file. Manufacturers wishing to provide an oral presentation on more than one drug product must submit a separate one-page summary, in PDF format, for each product.
3) **Submissions are limited to 1 page for each drug product**. Oral presentation summaries may not include references, package inserts or any other information on the reverse side of the document.
4) **Submissions must be clearly labeled as "Oral Presentation Summary" on the top of the page.**
5) **Submissions file names must be clearly labeled as "Oral Presentation Summary".**
6) Oral presentations must also be limited to peer reviewed published clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information. Posters, podium presentations and other such information will not be accepted.**
7) Oral presentations must be limited to sound clinical evidence and to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference format.

Failure to abide by all of these requirements upon submission will result in a rejection of the written comments and/or oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline. At no time should representatives of the pharmaceutical manufacturing entity contact the Clinical Support Contractor, UMass Clinical Pharmacy Services regarding this submission process. All inquires should be directed to the contact person listed below. Also, please refer to the Medicaid website (www.medicaid.alabama.gov) for additional information related to presentations, timelines, clinical comment submissions, and/or submission of supplemental rebate offers. Supplemental rebate offers should not be included in this submission to UMass Clinical Pharmacy Services, as these will not be reviewed by UMass Clinical Pharmacy Services nor forwarded to Alabama Medicaid. The supplemental rebate offer form is available on the Medicaid website. If you should have additional questions regarding this notice or if you have received this letter and are no longer the appropriate contact, please notify the Medicaid Clinical Services and Support Division at (334) 242-5050.

Sincerely,

Keisha Hawkins

Keisha Hawkins, BS, CPhT
PDL Administrator