HBCU 1886
UNIVERSITY OF MARYLAND EASTERN SHORE
SCHOOL OF PHARMACY AND HEALTH PROFESSIONS
DEPARTMENT OF PHARMACY PRACTICE AND ADMINISTRATION

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To whom it may concern:

I am writing this letter of comment in regards to the therapeutic alternative lists suggested for Farxiga (dapagliflozin), Jardiance (empagliflozin), Trulicity (dulaglutide), and Ozempic (semaglutide). For each of these drugs the proposed lists of therapeutic alternatives include options that are not appropriate for the majority of patients who are prescribed these agents. Trulicity and Ozempic belong to the glucagon-like peptide-1 receptor agonist (GLP-1 RA) class of drugs. Jardiance and Farxiga belong to the sodium-glucose co-transporter-2 inhibitor class of drugs. (SGLT2-i).

The American Diabetes Association Standards of Care in Diabetes – 2024 recommends that drugs that have shown benefits for ASCVD, heart failure, and DKD should be considered first when determining appropriate therapy for Type 2 Diabetes Mellitus. Specific medications in both classes have shown benefits in preventing atherosclerotic cardiovascular disease (ASCVD) events such as heart attacks and strokes as well as preventing worsening of diabetic kidney disease (DKD) in people with Type 2 Diabetes Mellitus. Specific medications in the SGLT2i class have indications for reduction in heart failure hospitalizations in people with Type 2 Diabetes Mellitus. Drugs in the DPP-4 inhibitor class are listed as therapeutic alternatives for all four agents. None of the medications in that class have shown benefits for ASCVD, heart failure, or DKD. They can be great agents in specific situations, but they are not reasonable to include as alternatives to drugs that are intended not just to lower glucose but also to improve comorbid conditions.

Cost and Care Delays

Providing medications in either class as therapeutic or other classes alternatives that have not shown benefits for important comorbidities will likely result in insurance providers requiring prior authorizations or other additional paperwork to obtain these medications. Placing barriers to obtain these medications creates delays in care, adds to administrative burden, and ultimately increases overall healthcare costs as time and resources must be devoted to those processes.

Jardiance and Farxiga

Jardiance and Farxiga are approved for use in heart failure and chronic kidney disease in **persons without Diabetes Mellitus**. SGLT-2 inhibitors are included in the American Heart Association heart failure treatment guidelines as one of the main pillars for treatment of heart failure with reduced ejection fraction. Having agents that are solely used to treat Type 2 Diabetes Mellitus listed as therapeutic alternatives will create confusion and unnecessary issues with access for patients being placed on these medications by their heart and kidney specialists.

Jardiance and Invokana (canagliflozin) are the only two agents in the SGLT-2 inhibitor class that have studies showing benefits in ASCVD, heart failure, and DKD in persons with diabetes mellitus. Listing Invokana as a therapeutic alternative is reasonable for Type 2 Diabetes but not for heart failure or chronic kidney disease in **persons without diabetes**. Steglatro (ertugliflozin) is listed a possible therapeutic alternative, but that agent is only indicated for reduction of blood glucose not ASCVD, heart failure, or DKD. Farxiga does not carry an indication for ASCVD benefit so it is not a good therapeutic alternative in terms of being preferred over Jardiance or Invokana for treatment of Type 2 Diabetes Mellitus. For

heart failure and chronic kidney disease in those without diabetes it is a reasonable alternative to Jardiance and vice versa.

Trulicity and Ozempic

The only GLP-1 RA agents that have shown ASCVD benefit are Trulicity, Ozempic, and Victoza. Trulicity remains the only drug in the GLP-1 receptor agonist (RA)class of drugs that has an FDA indication for primary prevention of atherosclerotic cardiovascular disease (ASCVD) events for individuals with Type 2 Diabetes Mellitus. Providing Victoza as preferred over Trulicity or Ozempic would also create a reduction in adherence as it is once a day compared to once a week. Decreased adherence often results in the requirement for more medications and poorer outcomes which ultimately results in increased overall healthcare costs. Byetta (exenatide), Bydureon (exenatide LAR), and Adlyxin (lixisenatide) have not shown an ASCVD benefit. These agents are appropriate therapeutic alternatives for Trulicity, Ozempic, and Victoza. SGLT-2 inhibitors with ASCVD benefit are reasonable alternatives but their effect on blood glucose and weight are more modest so they will not always the best alternative.

Conclusion

The therapeutic alternatives list as written does not differentiate between medication indications. It also includes medications that are not usually appropriate as SGLT-2 inihibitor and GLP-1 RA agents are often the practice guideline recommended first or second like agents depending on patient co-morbidities. Cost of drugs must be considered in relation to the cost savings from avoiding hospitalizations for ASCVD events, heart failure exacerbations, and decline in kidney function or kidney failure. The current list will likely result in delays in care, barriers to access, and inappropriate therapeutic selections.

Sincerely,

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