Drug List Development Process

To develop the sample $2 Drug List, the Innovation Center evaluated covered outpatient generic drugs across multiple factors including but not limited to:

- clinical role in therapy based on national treatment and medical society guidelines and public research;
- frequency of use among Medicare beneficiaries;
- cost of the drug (for the Part D sponsor) and associated financial impact of inclusion;
- rates of inclusion on Part D preferred generic formulary tiers;
- presence of prior authorization or step therapy requirements;
- inclusion on low-dollar retail and commercial formularies;
- inclusion on federal partner formularies (e.g., Veterans Affairs National Formulary);
- number of manufacturers and/or potential for supply interruptions; and
- presence on the American Geriatrics Society Beers Criteria®, Drug Enforcement Administration (DEA) scheduled substances, or other safety related categorizations.

The Innovation Center structured and consolidated information using the above criteria for each generic drug, developing a prioritized list of drugs suitable for potential inclusion. The information was then reviewed with an external technical expert panel (TEP) of physicians, pharmacists, and health policy experts, and their individual recommendations informed the sample list of drugs presented in this RFI.

Are there additional data sources, criteria, or considerations the Innovation Center should consider in developing future versions of the $2 Drug List?

When developing future versions of the $2 drug list, evidence-based and guideline-based medicine should be used as the standard criteria for updating the drug list. Additionally, if best practices exist for certain disease processes, the medications that are included in these recommendations should be added to the list. For example, there is strong evidence for guideline-directed medical therapy for heart failure so the addition of generic drugs used to treat the condition should be strongly considered for the list. Another consideration should be prevalence of disease in the national population, as the greater number of people affected by a disease should result in a greater availability of medication for that disease. This could mean including generic versions of medications such as epi-pens, or controller inhalers for important conditions.

Other considerations for a future drug list should consider what drugs are standard of care. One example of this is the use of warfarin (coumadin). More people are using direct oral anticoagulants (DOACs) instead of warfarin for anti-coagulation medication. Another medication on the current list that may be reevaluated is indapamide. Since hydrochlorothiazide, which is much more commonly used is on the list, the inclusion of indapamide seems redundant.

Additionally, the difference between the cost of the drug and the $2 price should be taken into consideration. Newer, more costly drugs would be of greater benefit being on the list than an older, cheaper drugs. Another factor for consideration when including a new drug should be the applicability of CMS quality measures. One example is looking at the ratio of prescription refills of short-acting albuterol vs. triple therapy for chronic obstructive pulmonary disease (COPD) (long-acting ICS-LABA/LAMA) and using this metric to consider including a generic inhaled corticosteroid-LABA or LAMA inhaler.

Drugs on this list should be tailored to Medicare beneficiaries who are generally 65 and older, especially if the drug has harmful side effects for older individuals. Drugs on the list may be used preferentially which could result in potential harm to older individuals. One example is the only GI drug on the list, metoclopramide, which has some significant potential side effects and could be problematic in the older individuals specifically if used chronically. There are other GI drugs available that are safer but not on the list. Antibiotics, topical antifungals, inhaled steroids, topical steroids, and vitamins or dietary supplements should be reevaluated for inclusion on the list.

Part D Sponsor Outreach and Education Efforts for Beneficiaries

We are seeking information about the best practices used by Part D sponsors' communications and marketing efforts to prescribers, beneficiaries, and their caregivers about the details of a given Part D plan, especially details on gaining access to low-cost drugs.

Please provide examples of specific marketing elements or techniques that have either been effective or ineffective at helping beneficiaries, and their prescribers navigate their Part D plan options. Are there specific marketing or outreach elements that have either been effective or ineffective with low-income populations? How could these examples be applied to the M2DL Model being developed?

There should be a well-designed, simple to use website that has all the necessary information and should be easily accessible by practitioners. The drug list could be incorporated through electronic medical records so practitioners can be notified, automatically, that a patient is eligible for a prescription that is on the list.

It is important to remember the audience when using marketing techniques. Since some patients are not familiar or comfortable with using the internet/technology it may be useful to also market through different channels such as major retail pharmacies like CVS or Walgreens. Additionally, it is important to work with the pharmacists to learn about reasons why or barriers to their participation and promotion of the drugs on the list.

How might outreach and educational efforts be most impactful for helping to reach members of underserved communities including but not limited to beneficiaries in rural, tribal, and geographically isolated communities to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes?

To help reach underserved communities it may also be beneficial to use major retail pharmacies for marketing. However, it may not be effective to go through Federally Qualified Health Centers since many of them have their own 340B programs. Another way to market this to underserved communities is to work with trusted local leaders to disseminate information on the community level. This could include creating a needs assessment for individual communities. One example explained by the American Heart Association focused on New Orleans where physicians have partnered with religious leaders to help improve blood pressure management and cardiovascular disease in the Black community ("For Black Churchgoers in New Orleans, Religious Beliefs May Influence Health Behaviors" by Laura Williamson). Working with trusted leaders and existing infrastructure found an improvement in diet, exercise, and cardiovascular health in these communities since the leaders are meeting communities where they are at.

Drug List Modifications

The ease of beneficiaries, pharmacists, and prescribers using the $2 Drug List is improved if the list is static. But with changes to the generic drug landscape and the dynamic nature of associated scientific evidence, updates to the list may be necessary.

How could future changes to the $2 Drug List be best communicated to beneficiaries, prescribers, pharmacies, and plans? How could changes to the $2 Drug List complement existing formulary update processes? With what frequency should the list be updated to balance both consistency with the need to respond to dynamic changes?

The update process should be flexible and reflect the needs of patients and the improvement and invention of drugs but should not be too frequent that it causes confusion on which medications are currently available. The processes need to be objective, transparent, and without financial or political influence. Patients should be able to submit medication for review and there should be experts reviewing the list to see how helpful or effective each medication is for Medicare beneficiaries. All this information, including the list, should be public and there should be a summary of changes when they are made.

Sample Drug List and Optional File Upload

Appendix 1: Machine Readable File: The sample $2 Drug List includes 101 drugs covering therapeutic uses across 15 clinical categories. The appendix specifies the 101 drugs at the level of RxCUI (RxNorm concept unique identifier), which uniquely identifies a drug with its active ingredient, strength, and formulation (e.g., atorvastatin 10mg tablets).

The sample $2 Drug List shared in this RFI represents a starting point for the Innovation Center's development of the M2DL Model which, pending development, could start as early as January 2027.

Optional: The Innovation Center looks forward to obtaining feedback from a variety of sources to inform the development of the model that maximizes beneficiary access to low-cost generic drugs including input on the sample $2 Drug List. Do you have further input for CMS consideration on the sample $2 Drug List?

The $2 Drug list should not disincentivize other drug discount programs like the Walmart program or the Mark Cuban Cost Plus program. Additionally, this program could inflict administrative burdens such as checking to see if a specific drug qualifies. The frequent updating of the list could also become burdensome.