Topic Brief: Pharmacy Formulary Restrictions

Date: 3/22/2024
Nomination Number: 1046

Purpose: This document summarizes the information addressing a nomination submitted on April 19, 2023 (Link to nomination) through the Effective Health Care Website. This information was used to inform Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: Policymakers often place formulary restrictions on medications to limit the use of ineffective treatments and to reduce overall costs. The nominator is concerned that formulary restrictions may result in patient harms due to delayed or sub-optimal treatment. Formulary restrictions may also exacerbate health disparities based on race and ethnicity.

Findings

The available evidence on this topic consists of relatively few studies that generally have weak study designs. A systematic review likely will reach inconclusive answers to the key questions.

Background

Approximately 66% of U.S. adults take prescription medicines.[1] At $1,432, the U.S. has the highest per capita pharmaceutical expenditure among peer nations.[2] A drug formulary is a system designed to identify the most effective, appropriate, safe and cost-effective medication for treating a given health condition.[3] To reduce or control pharmacy expenditures, policymakers may impose formulary restrictions which can include cost sharing measures like copayments, prior authorization, required step therapy regimens, preferred drug lists and quantity limits.[4] The procedures for establishing and managing restricted formularies have become standardized across the United States and similar countries such as Canada.[5]

There is controversy regarding the benefits and possible harms of drug formulary restrictions. Some studies have found that formulary restrictions can control costs without leading to apparent adverse effects on healthcare outcomes.[6, 7] Nevertheless, restricted formularies have engendered frequent criticisms and have been accused of being based on faulty premises.[8, 9] Formulary restrictions also exist in a complex framework of other factors, including physician attitudes about appropriate treatments, patient socioeconomic factors, and temporal changes in overall healthcare costs and insurance coverage.[10, 11] The nominators are interested in a systematic review that includes the most recent studies of the patient outcomes and economic consequences of formulary restrictions, as well as how restricted formularies may disproportionately affect vulnerable populations.

Scope

Key Questions

1. What are the overall effects of formulary prescribing restrictions on patient and economic outcomes?

2. Do formulary prescribing restrictions lead to disparities based on race, socioeconomic status (SES), age, or gender?

Table 1. Questions and PICOS (population, intervention, comparator, outcome, and setting)

Questions	Formulary restrictions and patient and economic outcomes
Population	Patients with any health condition Patient characteristics: age, gender, race/ethnicity, SES
Interventions	Formulary restrictions developed to meet requirements of third-party payers: • Cost sharing (copayment or coinsurance) • Prior authorization • Step therapy • Preferred drug lists • Dosage limits • Quantity limits
Comparators	No formulary restrictions or alternative restrictions
Outcomes	*Patient outcomes-* • Prescribing rates • Medication adherence (i.e., compliance, adherence, persistence, and discontinuation) • Clinical outcomes (i.e., any measure of patient health) *Economic outcomes-* • Total costs or total pharmacy costs • Healthcare resource utilization (i.e. physician visits, hospitalizations (inpatient or outpatient), and ER visits)
Setting	Studies conducted in the U.S. or in comparable national or regional healthcare systems

Assessment Methods

See Appendix A.

Summary of Literature Findings

Communication with the nominator of this topic identified two systematic reviews that had been published prior to the timeframe of our literature search.[4, 12] The literature search identified a total of 609 citations. These were reviewed for relevance by one reviewer, and those ratings were verified by a second reviewer. The second reviewer then reviewed the full-text articles to make a final determination of included studies. This process yielded two additional systematic reviews and eight primary research studies that were relevant to the topic's key questions. Review of reference lists of the four included systematic reviews identified one RCT and seven additional primary research studies that were published prior to the timeframe of the literature search (see Table 2 for summary of included studies).

A systematic review published in 2021[13] took a broad approach for identifying factors associated with uptake of newly approved medications into clinical practice. It included studies using data

from administrative databases and studies based on surveys or interviews of prescribers. None of the studies included in this systematic review were RCTs. The review identified ten studies that examined formulary or reimbursement restrictions as a barrier to prescribing new medications. Four of these[14-17] met the inclusion criteria for this topic brief and are described below. The review did not draw specific conclusions about the importance of formulary restrictions relative to other factors that affect the uptake of new medications into practice. The two earlier systematic reviews also addressed a broad spectrum of medications and addressed a variety of outcomes that are plausibly related to formulary restrictions.[4, 12] These reviews primarily focused on medication adherence rates and concluded that formulary restrictions are sometimes associated with lower rates of adherence. Review of the reference lists of these two reviews identified four studies that included data about clinical outcomes other than medication adherence (one RCT,[18] two studies with pre-post study designs,[19, 20] and one study with a retrospective cohort design[21]). These studies are also described below.

A systematic review published in 2022[22] examined barriers to the use of medications for the treatment of alcohol use disorder. It identified 23 relevant studies, but these mostly were reports of surveys and/or interviews that focused on provider perceptions. None of the included studies included data on the relationship of formulary restrictions to actual prescribing rates or clinical outcomes.

The single randomized controlled trial that was identified in our searches used a cluster randomization approach.[18] The study population was patients hospitalized for acute myocardial infarction who were followed for three years following discharge. The study included 5855 patients who were grouped by 2980 insurance plans. The plans were randomized to either full coverage (i.e., no co-payments for filled prescriptions) of all cardiac medications or "usual" coverage in which some co-payments could be charged to patients. The study found that medication adherence was modestly better in the patients with expanded insurance coverage, but the rate of the primary clinical outcome (time to first subsequent major cardiac event) did not differ between the groups.

Of the ten included primary studies that used time series or pre-post study designs, five[19, 20, 23-25] were based on data from the United States. The other studies included two from Canada,[14, 17] one from the United Kingdom,[16] one from Spain,[15] and one from Thailand.[26] All of these studies examined single classes of medications that were relatively new at the time the data were collected and measured prescribing rates before and after easing of formulary restrictions in national or regional health systems. One U.S. study[24] and three studies from other countries[14, 15, 17] focused on prescribing rates and consistently found higher utilization of certain medications after formulary restrictions were eased. The study from Thailand[26] found that prescribing rates went down when formularies added restrictions for a group of medications considered "non-essential."

Five of the studies with pre-post designs attempted to determine whether changes in formulary restrictions led to short-term changes in clinical outcomes or other measures of the quality of care. A U.S. study of a formulary change to reduce patient co-pays for diabetes medications did not find statistically significant changes in measures of short-term complications attributed to diabetes.[23] A study using national VA data examined a formulary change in which an inhaled medication used for COPD was removed from the national formulary.[25] This example of "non-medical switching" of medications was not found to be associated with measures of COPD exacerbations. In the United Kingdom, a program to reduce financial barriers for prescribing cancer drugs was found to be associated with an increased use of drugs that were not supported

by clinical guideline recommendations but no increase in proscribing of guideline-recommended drugs.[16]

Two U.S. studies with pre-post designs examined the effect of a formulary change in which a formulary restriction was implemented to limit the maximum daily dose of buprenorphine for patients being treated for opioid use disorder. One study[20] examined a cohort of patients who were followed for four months following institution of the formulary restriction and reported a modest increase in a measure of relapse rates compared to a comparison patient group that was followed prior to the formulary change. However, a second study[19] examined a similar formulary change but followed patients for 18 months after the change. This study found a short-term increase in relapse rates after the change, but the rates returned to the baseline levels shortly thereafter. This second study suggests that the short-term follow-up period in the first study provided spurious findings.

Four of the included studies examined other aspects of clinical care that may be associated with formulary restrictions. Two U.S. studies having retrospective cohort designs used Medicare data in which patients were stratified by the level of formulary restrictions for certain classes of medications.[21, 27] Both studies found that prescribing of newer (recently released) medications was higher among patients covered by formularies with fewer restrictions on the prescribing of those drugs. A cross-sectional study using a U.S. national pharmacy claims database found that formulary restrictions were associated with choice of narcotic pain medications prescribed by physicians.[28] A study based on an epidemiological model of care for HIV estimated the effect of formulary restrictions on access to antiviral medications.[29] This analysis found an increased rate of predicted adverse events with increased formulary restrictions.

The previously described studies generally did not examine patient sub-groups or sources of disparities related to formulary restrictions. However, a study using a retrospective cohort design examined the utilization of hydroxyurea for children with sickle cell anemia.[30] This study used data from the U.S. military health system in which there were no formulary restrictions on hydroxyurea prescribing. The study found no disparities in hydroxyurea use based on patient gender or family income. Because the study had no data on patients who encountered formulary restrictions, it was not able to show whether there was an interaction between the patient/family factors and formulary policies.

Table 2. Literature identified for each Question

Question	Systematic reviews (11/2020-11/2023)	Primary studies (11/2018-11/2023)
Question 1: Formulary restrictions, patient & economic outcomes	Total: 4 • Cochrane 0 • AHRQ 0 • Other 4	Total: 15 • RCT 1 • Controlled pre-post: 10 • Retrospective cohort 2 • Cross-sectional 1 • Economic modeling 1
Question 2: Disparities based on race, SES, age, or gender	Total: 0	Total: 1 • Retrospective cohort 1

Summary of Selection Criteria Assessment

The literature searches for this topic (which included a Medline search and reviews of studies identified in four systematic reviews published within the last ten years) found a relatively small number of studies, and most of these studies used study designs with methodological limitations. The most prevalent outcome used in the studies was medication prescribing rate. Few studies included long-term patient outcome data. A systematic review on this topic is unlikely to reach definitive answers to the key questions.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years (11/2020-11/2023) on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
  - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
  - EHC Program https://effectivehealthcare.ahrq.gov/
  - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
  - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
  - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
  - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- University of York Centre for Reviews and Dissemination database https://www.crd.york.ac.uk/CRDWeb/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- PubMed https://www.ncbi.nlm.nih.gov/pubmed/
- Campbell Collaboration http://www.campbellcollaboration.org/
- McMaster Health System Evidence https://www.healthsystemsevidence.org/
- UBC Centre for Health Services and Policy Research http://chspr.ubc.ca/
- Joanna Briggs Institute https://jbi.global/
- WHO Health Evidence Network https://www.who.int/europe/groups/health-evidence-network-(hen)

Impact of a New Evidence Review.

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed and PsycInfo for the last five years (November 2018-November 2023). We also reviewed the reference lists of four systematic reviews published since 2014. We classified identified studies by question and study design to estimate the size and scope of a potential evidence review. For KQ 1 we identified 15 published

studies and four systematic reviews that were published within the last 15 years. For KQ 2 we identified 1 published study published over the same time period.

All Search Strategies (*note: separate by KQ in EndNote and in search strategy, PRISMA format*)**:**

Ovid MEDLINE ALL (1946 to November 16, 2023)
Date searched: November 17, 2023
1 exp *"Formularies as Topic"/ (1687)
2 (((drug$1 or medicine$1) adj list$1) or "essential medicine$1" or "preferred drug$1" or formular*).ti,ab,kf. (9295)
3 or/1-2 (9756)
4 Cost Sharing/ or For-Profit Insurance Plans/ or Health Maintenance Organizations/ or Insurance Coverage/ or Insurance, Pharmaceutical Services/ or exp Managed Care Programs/ or Medicaid/ or Medicare/ or Medicare Part D/ or Not-For-Profit Insurance Plans/ or Prepaid Health Plans/ or Prior Authorization/ (117725)
5 (benefit$1 or coinsur* or "co-insur*" or copay* or "co-pay*" or "cost shar*" or exclude$1 or exclusion$1 or HMO$1 or "health maintenance organization" or insur* or "managed care" or Medicaid or Medicare or "non-medical switching" or "nonmedical switching" or payer$1 or "prior authori?ation" or preauthori* or "pre-authori*" or removal or removed or restrict* or step or stepped or tier$1 or withdraw$2).ti,ab,kf. (3152778)
6 or/4-5 (3195208)
7 (outcome$1 or patient or patients).hw. or Medication Adherence/ or Patient Readmission/ or Patient Safety/ or Value-Based Health Insurance/ or Value-Based Purchasing/ (2142789)
8 (adheren$2 or inpatient$1 or morbidit* or mortality or outcome$1 or outpatient$1 or patient$1 or readmission$1 or readmitted or value-based).ti,ab,kf. (9691637)
9 or/7-8 (10284428)
10 and/3,6,9 (2054)
11 limit 10 to english language (2009)
12 11 not (case reports or comment or editorial or letter or news).pt. (1972)
13 limit 12 to yr="2020 - 2024" (455)
14 13 and ((meta-analysis or systematic review).pt. or (meta-anal* or metaanal* or ((evidence or review or scoping or systematic or umbrella) adj3 (review or synthesis))).ti. or cochrane.jw.) (54
15 (((integrative or interpretive or "mixed method" or "mixed methods" or qualitative or realist or thematic) adj3 (synthes* or review*)) or ((framework or narrative) adj2 synthes*)).ti,ab,kf. (31464
16 (mega-ethnograph* or megaethnograph* or meta-aggregat* or metaaggregat* or meta-ethnograph* or metaethnograph* or meta-interpret* or metainterpret* or meta-method* or metamethod* or meta-narrative* or metanarrative* or meta-study or metastudy or meta-synthe* or metasynthe* or meta-summary or metasummary or meta-triangulat* or metatriangulat*).ti,ab,kf. (3778)
17 ((qualitative adj2 (literature or paper or papers or research or study or studies)) and (synthes* or "systematic review" or "systematic reviews")).ti,ab,kf. (9044)
18 ((qualitative adj2 (literature or paper or papers or research or study or studies)) and ("literature search" or "literature searching" or "literature searches")).ti,ab,kf. (969)
19 ((qualitative adj2 (literature or paper or papers or research or study or studies)) and ("quality assessment" or "critical appraisal" or checklist*)).ti,ab,kf. (2990)
20 (((mixed or integrative) adj2 (method* or research or study or studies)) and (synthes* or "systematic review" or "systematic reviews")).ti,ab,kf. (6614)

21 (((mixed or integrative) adj2 (method* or research or study or studies)) and ("literature search" or "literature searching" or "literature searches")).ti,ab,kf. (709)
22 (((mixed or integrative) adj2 (method* or research or study or studies)) and ("quality assessment" or "critical appraisal" or checklist*)).ti,ab,kf. (1831)
23 (CERQUAL or CONQUAL or JBI-QARI or QualSys or "Mixed Methods Appraisal Tool" or MMAT).ti,ab,kf. (1774)
24 (Noblit and Hare).ab. (103)
25 or/15-24 (41751)
26 and/13,25 (9)
27 limit 12 to yr="2018 - 2024" (662)
28 27 and ((controlled clinical trial or randomized controlled trial).pt. or (((control or controls) adj5 group$1) or controlled or random* or trial*).ti,ab,kf.) (140)
29 28 not (14 or 26) (114)
30 27 and (Comparative Study/ or Controlled Before-After Studies/ or Follow-Up Studies/ or Interrupted Time Series Analysis/ or Program Evaluation/ or Prospective Studies/ or Retrospective Studies/ or ("before after" or ((comparative or evaluation) adj study) or follow-up or "interrupted time" or "difference in difference$1" or prospective$2 or retrospective$2).ti,ab,kf.) (181)
31 30 not (14 or 26 or 29) (134)
32 Focus Groups/ or "Interviews as Topic"/ or Qualitative Research/ (157452)
33 ("focus group$1" or "grounded theory" or interview* or phenomenolog* or qualitative*).ti,ab,kf. (769055)
34 (experienc* or opinion* or perception* or perspective* or prefer*).ti,ab. (2685476)
35 or/32-34 (3193436)
36 and/27,35 (270)
37 36 not (14 or 26 or 29) (197)
38 37 and ((Canada or England or Ireland or "United States").cp. or (American or British or Canadian or pharmac*).jw.) (158)

Ovid EBM Reviews - Cochrane Central Register of Controlled Trials (October 2023)
Date searched: November 17, 2023
1 "Formularies as Topic"/ or Formularies, Dental as Topic/ or Formularies, Homeopathic as Topic/ or Formularies, Hospital as Topic/ (30)
2 (((drug$1 or medicine$1) adj list$1) or "essential medicine$1" or "preferred drug$1" or formular*).ti,ab. (657)
3 or/1-2 (670)
4 Cost Sharing/ or For-Profit Insurance Plans/ or Health Maintenance Organizations/ or Insurance Coverage/ or Insurance, Pharmaceutical Services/ or exp Managed Care Programs/ or Medicaid/ or Medicare/ or Medicare Part D/ or Not-For-Profit Insurance Plans/ or Prepaid Health Plans/ or Prior Authorization/ (1618)
5 (benefit$1 or coinsur* or "co-insur*" or copay* or "co-pay*" or "cost shar*" or exclude$1 or exclusion$1 or HMO$1 or "health maintenance organization" or insur* or "managed care" or Medicaid or Medicare or "non-medical switching" or "nonmedical switching" or payer$1 or "prior authori?ation" or preauthori* or "pre-authori*" or removal or removed or restrict* or step or stepped or tier$1 or withdraw$2).ti,ab. (313845)
6 or/4-5 (314070)
7 (outcome$1 or patient or patients).hw. or Medication Adherence/ or Patient Readmission/ or Patient Safety/ or Value-Based Health Insurance/ or Value-Based Purchasing/ (462436)
8 (adheren$2 or adverse or inpatient$1 or morbidit* or mortality or outcome$1 or outpatient$1 or patient$1 or readmission$1 or readmitted or safety or value-based).ti,ab. (1447951)

9 or/7-8 (1495623)
10 and/3,6,9 (207)
11 limit 10 to yr="2018 -Current" (70)

Ovid APA PsycInfo (1806 to November Week 1 2023)
Date searched: November 17, 2023
1 (((drug$1 or medicine$1) adj list$1) or "essential medicine$1" or "preferred drug$1" or formular*).ti,ab. (917)
2 exp Employee Health Insurance/ or Health Insurance/ or Health Maintenance Organizations/ or Insurance/ or Managed Care/ or Medicaid/ or Medicare/ or "Underinsured (Health Insurance)"/ or "Uninsured (Health Insurance)"/ (16501)
3 (benefit$1 or coinsur* or "co-insur*" or copay* or "co-pay*" or "cost shar*" or exclude$1 or exclusion$1 or HMO$1 or "health maintenance organization" or insur* or "managed care" or Medicaid or Medicare or payer$1 or "prior authori?ation" or preauthori* or "pre-authori*" or removal or removed or restrict* or step or stepped or switch* or tier$1 or withdraw$2).ti,ab. (531414)
4 or/2-3 (534054)
5 Patients/ or Geriatric Patients/ or Hospitalized Patients/ or Medical Patients/ or Outpatients/ or Patient Safety/ or Psychiatric Hospital Readmission/ or Psychiatric Patients/ or Treatment Compliance/ (116922)
6 (adheren$2 or adverse or inpatient$1 or morbidit* or mortality or outcome$1 or outpatient$1 or patient$1 or readmission$1 or readmitted or safety or value-based).ti,ab. (1313425)
7 or/5-6 (1326006)
8 and/1,4,7 (218)
9 limit 8 to english language (214)
10 limit 9 to yr="2020 -Current" (19)
11 limit 10 to ("0830systematic review" or 1200 meta analysis) (1)
12 limit 10 to 1300 metasynthesis (0)
13 limit 9 to yr="2018 -Current" (34)
14 limit 13 to "0300 clinical trial" (1)
15 limit 13 to ("0430 followup study" or "0451 prospective study" or "0453 retrospective study" or 1800 quantitative study or 2100 treatment outcome) (21)
16 limit 13 to ("0600 field study" or "0700 interview" or "0750 focus group" or 1600 qualitative study) (3)

EBSCOhost CINAHL Plus Full Text (Inception to November 16, 2023)
Date searched: November 17, 2023
S1 MH ("Drugs, Essential" OR "Formularies") (2,425)
S2 TI ("drug list*" OR "medicine list*" OR "essential medicine*" OR "preferred drug*" OR formular*) OR AB ("drug list*" OR "medicine list*" OR "essential medicine*" OR "preferred drug*" OR formular*) (4,980)
S3 S1 OR S2 (6,246)
S4 MH ("Insurance" OR "Insurance, Health" OR "Insurance, Health, Reimbursement" OR "Insurance Benefits" OR "Insurance Coverage" OR "Insurance, Pharmaceutical Services" OR "Community-Based Health Insurance" OR "Health Insurance Exchanges" OR "Health Benefit Plans, Employee" OR "Managed Competition" OR "Medicaid+" OR "Medicare" OR OR "Value-Based Insurance" OR "Managed Care Programs+") (96,732)
S5 TI (benefit* OR coinsur* OR "co-insur*" OR copay* OR "co-pay*" OR "cost shar*" OR exclude* OR exclusion* OR HMO* OR "health maintenance organization" OR insur* OR "managed care" OR Medicaid OR Medicare OR "non-medical switching" OR "nonmedical

switching" OR payer* OR "prior authorization" OR preauthori* OR "pre-authori*" OR removal OR removed OR restrict* OR step OR stepped OR tier* OR withdraw*) OR AB (benefit* OR coinsur* OR "co-insur*" OR copay* OR "co-pay*" OR "cost shar*" OR exclude* OR exclusion* OR HMO* OR "health maintenance organization" OR insur* OR "managed care" OR Medicaid OR Medicare OR "non-medical switching" OR "nonmedical switching" OR payer* OR "prior authorization" OR preauthori* OR "pre-authori*" OR removal OR removed OR restrict* OR step OR stepped OR tier* OR withdraw*) (746,898)
S6 S4 OR S5 (793,355)
S7 MH ("Treatment Outcomes" OR "Outcome Assessment" OR "Outcomes Health Care" OR "Fatal Outcome" OR "Medication Compliance" OR "Readmission" OR "Safety") (550,585)
S8 TI (adheren* OR inpatient* OR morbidit* OR mortality OR outcome* OR outpatient* OR patient* OR readmission* OR readmitted OR value-based) OR AB (adheren* OR inpatient* OR morbidit* OR mortality OR outcome* OR outpatient* OR patient* OR readmission* OR readmitted OR value-based) (2,694,377)
S9 S7 OR S8 (2,870,268)
S10 S3 AND S6 AND S9 Limiters - Published Date: 20201101-20231231; English Language; Exclude MEDLINE records; Publication Type: Meta Analysis, Systematic Review (8)
S11 S3 AND S6 AND S9 Limiters - Published Date: 20200101-20231231; English Language; Exclude MEDLINE records; Publication Type: Meta Synthesis (0)
S12 S3 AND S6 AND S9 Limiters - Published Date: 20180101-20231231; English Language; Exclude MEDLINE records; Publication Type: Clinical Trial, Randomized Controlled Trial (2)
S13 S3 AND S6 AND S9 AND ("before after" OR "comparative study" OR "evaluation study" OR follow-up OR "interrupted time" OR "difference in difference*" OR prospective* OR retrospective*) Limiters - Published Date: 20180101-20231231; English Language; Exclude MEDLINE records; Publication Type: Case Study (0)
S14 S3 AND S6 AND S9 AND ("focus group" OR "grounded theory" OR interview* OR phenomenolog* OR qualitative* OR experienc* OR opinion* OR perception* OR perspective* OR prefer*) Limiters - Published Date: 20180101-20231231; English Language; Exclude MEDLINE records (78)

PROSPERO
Date searched: November 17, 2023
("drug list" or "medicine list" or "essential medicine" or "preferred drug" or formulary) and (adherence or adherent or adverse or inpatient or morbidity or mortality or outcome or outpatient or patient or readmission or readmitted or safety or value-based) AND (Systematic Review OR Meta-Analysis OR Qualitative synthesis):RT WHERE CD FROM 17/11/2021 TO 17/11/2023 (50)

ClinicalTrials.gov
Date searched: November 17, 2023
"drug list" OR "medicine list" OR "essential medicine" OR "preferred drug" OR formulary | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | First posted from 11/17/2020 to 11/17/2023 (34)

Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change, if a partner organization would use this evidence review to influence practice, and if the topic supports a priority area of AHRQ or the Department of Health and Human Services.

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes.
1b. Is the nomination a request for an evidence report?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes. The premise is that formulary restrictions may prevent patients from receiving medications that may be associated with better clinical outcomes than the medications currently being used by patients for their conditions.
2. Importance	
2a. Represents a large proportion of the population or national health priorities; presents a significant disease burden; addresses health disparities/equity	Yes. Approximately 66% of U.S. adults take prescription medicines.[1] Per capita pharmaceutical expenses in the U.S. were $1432 in 2021.[2]
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. Formulary restrictions are used by healthcare systems that provide care to lower income and disadvantaged populations, such as VA and Medicaid programs.
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. Medications newly approved by the FDA often are high-priced and subject to formulary restrictions.
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	No. We identified four systematic reviews published in the last ten years. The studies included in these reviews generally had methodological limitations and examined only a limited range of clinical outcomes.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	No. Formulary policies are generally mature and consistent across U.S. systems such as managed care programs, Medicaid programs, and the VA system.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	No.
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	*Size/scope of review:* The literature search for the last ten years identified one cluster RCT and 15 studies that had observational study designs. The studies generally had a limited range of clinical outcomes.
6. Value	

6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change and supports a priority of AHRQ or Department of Health and Human Services	Yes.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes. The evidence report will be used to advocate at state and federal levels for third-party payer prior authorization and step therapy policies that support patient well-being.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality