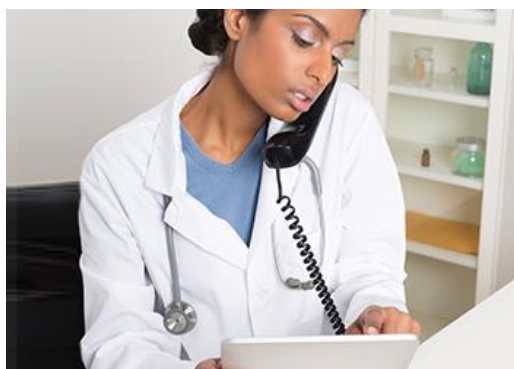


Antimicrobial Stewardship Strategy:

Formulary restriction with preauthorization

Preapproval of restricted antimicrobials before or shortly after dispensing the drug to ensure adherence to institutional criteria.



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Priority Level: **B**

Difficulty Level: **3**

Program Stage:

- Early
- Intermediate
- ✓ Advanced

Antimicrobial Stewardship

Outcomes:

- Drug utilization outcomes
- Prescribing outcomes
- Clinical outcomes
- Reduction of *Clostridium difficile* infection
- Reduction in antimicrobial-resistant organisms

For more information on these criteria and how they were developed, please see the [Antimicrobial Stewardship Strategy Criteria Reference Guide](#).

Description

This is an overview and not intended to be an all-inclusive summary. As a general principle, patients must be monitored by the health care team after changes to therapy resulting from recommendations made by the antimicrobial stewardship team.

Restrictions may be placed on the prescribing of certain antimicrobials on a hospital's formulary (see [Formulary restriction](#)). Such restrictions may be based on who can prescribe an antimicrobial (e.g., certain services or expertise), or on acceptable criteria for use of the antimicrobial in the institution. Formulary restriction with preauthorization is one way to ensure adherence to such restrictions.

Formulary restriction with preauthorization involves the preapproval of orders before dispensing a drug. Approval is often obtained through consultation between the prescriber and someone responsible for assessing the appropriateness of the request (often an infectious disease specialist and/or infectious disease pharmacist).

Implementation may occur in a number of ways:

- A member of the antimicrobial stewardship program is contacted (often via pager or phone) directly by the prescriber (or in some institutions, by the pharmacy) when a request for a restricted antimicrobial is received. Then, the antimicrobial is approved if indicated based on the restriction criteria, or alternatives are recommended.
- An approach similar to the one above may be used, but through consultation with an infectious disease specialist instead.

- A preauthorization form (or computerized physician order entry) can be used, in which the prescriber must indicate the rationale for the antimicrobial. The form is then reviewed prior to dispensing the drug.
- In a less formal program, clinical pharmacists (rather than a specific antimicrobial stewardship team member) contact the prescriber when the indication for the antimicrobial does not conform to restrictions.
- Some facilities have individuals available/accessible 24/7 for drug approval; alternatively, approval may be available only during prime working hours, with a short course dispensed until the request can be reviewed (e.g., on the next work day). Note that the latter approach has led to clinicians placing orders after hours.¹

Formulary restriction with preauthorization is considered a “front-end” strategy, because an intervention occurs before the drug is made available. It is also considered a “restrictive” (rather than an “educational/persuasive”) stewardship approach. This strategy may be used in conjunction with [prospective audit with intervention and feedback](#) to oversee both initial and ongoing use of restricted agents.

Advantages

- One of the two core stewardship strategies (in addition to [prospective audit with intervention and feedback](#)) as identified in the Infectious Diseases Society of America/Society for Healthcare Epidemiology of America guidelines.²
- Provides education directly to the prescriber at the time of the drug request.
- Can result in early and significant reductions in antimicrobial use and costs. It may also improve the appropriateness of the initial use of restricted agents.²
- An effective way of controlling/limiting use of specific antimicrobials in the setting of a nosocomial outbreak.
- Recording and collating restricted antimicrobial requests and interventions can provide useful information about form and guideline adherence and identify educational targets.
- The degree of monitoring/approval is flexible; specific agents can be targeted as required if resources are limited.

Disadvantages

- Resource-intensive; ideally requires regular, consistent availability of knowledgeable individuals for drug approval. Institutions may not have these resources readily or consistently available—additional staffing may be required.
- Prescribers may perceive a loss of prescribing autonomy if approval from another individual is required.
- Potential for prescribers to subvert the system (e.g., exaggerate the severity of illness) to gain approval. (Real-time chart review to confirm rationale can minimize this risk, but it requires additional resources.)
- Potential for patient safety issues due to a delay in providing patients with needed antimicrobial therapy while awaiting drug approval. (One solution may be a policy of providing the drug within a specified time in case of authorization delay.)

- Assessment of appropriateness of therapy occurs at the time of initial prescription; further decisions/modification of therapy is left to the prescriber (unless ongoing monitoring by the antimicrobial stewardship team is also provided).
- Effects of this strategy on overall antimicrobial use and resistance trends need to be monitored to ensure it does not simply result in a shift from certain antimicrobial classes to others.

Requirements

- Consistent availability of an individual capable of confidently assessing the appropriateness of antimicrobial requests. Typically this involves a physician or pharmacist with specific infectious diseases training.
- Policies and administration must provide sufficient support and authority to the antimicrobial stewardship team for the approval process to have an impact.

Associated Metrics

- Time from initial prescription to patient receiving antimicrobial therapy (to ensure the process does not result in undue delays of patient treatment).
- Appropriate use of restricted antimicrobials and feedback to individual prescribers.
- Antimicrobial use/costs, especially pertaining to restricted antimicrobials.
- Workload measurements for individual(s) providing authorization.

References

1. LaRosa LA, Fishman NO, Lautenbach E, Koppel RJ, Morales KH, Linkin DR. Evaluation of antimicrobial therapy orders circumventing an antimicrobial stewardship program: investigating the strategy of “stealth dosing.” *Infect Control Hosp Epidemiol.* 2007;28:551–6.
2. Dellit TH, Owens RC, McGowan Jr JE, Gerding DN, Weinstein RA, Burke JP, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis.* 2007;44(2):159–77. Available from: <http://cid.oxfordjournals.org/content/44/2/159.long>.

Additional Useful References

Select articles to provide supplemental information and insight into the strategy described and/or examples of how the strategy was applied; not a comprehensive reference list. URLs are provided when materials are freely available on the Internet.

- Buising K. Formularies and antimicrobial approval systems. In: Duguid M, Cruickshank M, editors. *Antimicrobial stewardship in Australian hospitals 2011*. Chapter 2. Sydney, Australia: Australian Commission on Safety and Quality in Health Care; 2010. Available from: <http://www.safetyandquality.gov.au/wp-content/uploads/2011/01/Antimicrobial-stewardship-in-Australian-Hospitals-2011.pdf>

- Griffith M, Postelnick M, Scheetz M. Antimicrobial stewardship programs: methods of operation and suggested outcomes. *Exp Rev Anti Infect Ther*. 2012;10(1):63–73.

Includes methods and drawbacks for formulary restriction and preauthorization.

- Reed EE, Stevenson KB, West JE, Bauer KA, Goff DA. Impact of formulary restriction with prior authorization by an antimicrobial stewardship program. *Virulence*. 2013;4(2):158–62. Available from: <http://www.tandfonline.com/doi/full/10.4161/viru.21657>
- White AC, Atmar RL, Wilson J, Cate TR, Stager CE, Greenberg SB. Effects of requiring prior authorization for selected antimicrobials: expenditures, susceptibilities, and clinical outcomes. *Clin Infect Dis*. 1997;25:230–9. Available from: <http://cid.oxfordjournals.org/content/25/2/230.long>

Samples/Examples

- [Example: Alberta Health Services - Pre-authorization Form for Restricted and Non-formulary Antibiotics](#)

These documents have been generously shared by various health care institutions to help others develop and build their antimicrobial stewardship programs. We recommend crediting an institution when adopting a specific tool/form/pathway in its original form.

Examples that contain clinical or therapeutic recommendations may not necessarily be consistent with published guidelines, or be appropriate or directly applicable to other institutions. All examples should be considered in the context of the institution's population, setting and local antibiogram.

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Links with Other Strategies

- [Clinical decision support systems/computerized physician order entry](#)
- [Formulary restriction](#)
- [General antimicrobial order forms](#)

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For further information

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Example: Alberta Health Services - Pre-authorization Form for Restricted and Non-formulary Antibiotics



Patient Label Here

Antibiotic Form

This form must be completed when prescribing non-formulary (NF) antimicrobials and select restricted antimicrobials for

- Inpatients
- Outpatients-Emergency, Home Parenteral Therapy, Dayward, Outpatient Clinics

Do not write or affix labels in this space

Restricted Antibiotics * †	
Daptomycin	Ertapenem Imipenem Linezolid IV / PO Meropenem Tigecycline
* For restricted antifungals, please use the Antifungal Form, CH-1057	
† See http://intraweb01.albertahealthservices.ca/pharmacy/ahs_formulary/criteria_of_use_report.aspx for Clinical Antibiotic Guidelines	
Date (yyyy-Mon-dd)	
Antimicrobial Requested	
Dosage	Duration of Therapy
Antimicrobial Allergies (describe reaction)	
Indication	<input type="checkbox"/> Community-acquired
	<input type="checkbox"/> Hospital-acquired
Organisms	<input type="checkbox"/> Suspected
	<input type="checkbox"/> Culture-proven
Concurrent Antimicrobials	
Serum Creatinine	Weight (kg)
Prescriber (print name)	Program
Prescriber Signature	Date (yyyy-Mon-dd)
Please send completed form to Pharmacy IMMEDIATELY	
Pharmacy use only	Date (yyyy-Mon-dd)
Formulary alternative(s) suggested	
Accepted <input type="checkbox"/> Yes <input type="checkbox"/> No Reason:	
Prescriber	Pharmacist

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