

 National Policy <input checked="" type="checkbox"/> <b>HSE AMRIC Reserve Antimicrobials Policy</b>			
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0	2016	Carbapenems only restricted antimicrobials listed. Pre-authorisation guidance of restricted antimicrobials advised 24/7.
1	2024	Full WHO AWaRe classification updated, antivirals and antifungals added. Pre- and post- authorisation of Reserve antimicrobials. Change "Restricted" to "Reserve" as per WHO.

### Publication Information

**Topic:**

Classification of antimicrobials in to Access, Watch and Reserve groups and the workflow for providing pre- and post- authorisation of Reserve antimicrobials.

**National Group:**

Antimicrobial Resistance and Infection Control (AMRIC)

**Short summary:**

HSE AMRIC advise that all acute hospitals have a Reserve antimicrobial policy in place. HSE AMRIC advocate for an Access, Watch and Reserve list of antimicrobials as adapted in this policy. This policy includes detail on pre- and post- authorisation of Reserve antimicrobials.

## Contents

1.1 Introduction .....	4
1.2 Purpose.....	5
1.3 Scope of this policy .....	5
1.3.1 Target users .....	5
1.3.2 Target population .....	5
1.4 Objective .....	5
1.5 Outcomes.....	6
1.6 Disclosure of interests .....	6
1.7 Rationale .....	6
1.8 Supporting evidence.....	6
1.9 Suggested citation.....	7
1.10 Governance.....	7
2.0 Implementation plan .....	8
2.1 Procedure for prescribing and dispensing reserve antimicrobials .....	9
3.0 Sustainability .....	11
3.1 Monitoring and evaluation .....	11
4.0 Review and Update .....	12
5.0 References.....	13
6.0 Glossary of terms .....	14
Appendix 1: AMRIC AWaRe categorisation .....	15
Appendix 2: Monitoring and Evaluation .....	18
Appendix 3: Members of the AMRIC Oversight committee .....	19
Appendix 4: Members of the AMRIC Advisory committee.....	20
Appendix 5: Members of the Policy Development Group.....	21
Appendix 6: Members of HSE AMRIC Acute Guidance Governance Group.....	22
Figure 1 Workflow for use of reserve antimicrobial agents.....	10
Table 1 WHO definition of Access, Watch and Reserve antimicrobial categorisation	4
Table 2 Access, Watch and Reserve categorisation of antimicrobials .....	15-17
Table 3 Monitoring and evaluation of Reserve antimicrobial policy .....	18

## 1.1 Introduction

Antimicrobial resistance (AMR) is a threat to global health and development and it contributes to millions of deaths worldwide each year<sup>1</sup>. Inappropriate use and overuse of antimicrobials are driving an increase in AMR and have a detrimental impact on the effectiveness of these critical medicines. The Global Action Plan on AMR published by the World Health Organisation (WHO) is working to improve the surveillance of antimicrobial resistance and reduce inappropriate antimicrobial consumption<sup>2</sup>. There is a recognized need for high-quality resources to improve antimicrobial prescribing globally. To address this need, a pragmatic approach was taken by WHO to develop actionable guidance for empiric antimicrobial use<sup>2</sup>.

The WHO have developed a classification system for antimicrobials to address issue of antimicrobial resistance. The WHO developed a framework based on three different categories; Access, **Watch and Reserve**, which all together forms the **AWaRe** categorization of antibiotics.

<b>Access<sup>2</sup></b>	Access antibiotics are antibiotics with a narrow spectrum of activity, generally with fewer side effects, a lower potential for the selection of antimicrobial resistance and of lower cost. They are recommended for the empiric treatment of most common infections and should be widely available.
<b>Watch</b>	Watch antibiotics generally have a higher potential for the selection of antimicrobial resistance and are more commonly used in sicker patients in the hospital facility setting. They should be carefully monitored to avoid overuse.
<b>Reserve</b>	Reserve antibiotics are last-resort antibiotics that should only be used to treat severe infections and on the advice of an infection specialist.

*Table 1 WHO definition of Access, Watch and Reserve antimicrobial categorisation*

Antimicrobial prescribing guidelines in all Irish hospitals should include a list that stipulates which antimicrobials are Reserve (approval of an infection specialist is required), Watch (for treatment of specific conditions or by specific specialties) and Access (preferred agents as per empiric antimicrobial guidance)<sup>2</sup>.

The WHO AwaRe categorisation has been adapted by the Antimicrobial Resistance and Infection Control (AMRIC) team to the categorisation in this document (Appendix 1); this is for consistency with the well-established green/red categorisation in community settings, antimicrobials approved for use in the HSE, inclusion of

antivirals and antifungals many of which are already Reserve agents in hospitals, and taking account of other national AMS work. Individual hospitals may decide due to local resistance data, local concerns pertaining to rates of *C difficile* and/or safety concerns that the Access or Watch categories may require local adjustment. The 3<sup>rd</sup> generation cephalosporins and/or the quinolones may be considered Reserve antimicrobial in some sites for example where *C difficile* rates are a concern. It is recommended that antimicrobials already in the “Reserve” category of this policy are not amended in an effort to preserve these agents for use in resistant infections only.

The HSE published the, “Antimicrobial Stewardship Guidance for all Healthcare settings” in Aug 2022 recommending the implementation of a Reserve use antimicrobial list in all hospitals<sup>3</sup>. Restriction of antimicrobials is a component of many AMS programmes worldwide. Processes for use of antibiotics in Reserve category must be designed so they do not delay prompt access to essential antimicrobial treatment for service users who need it<sup>3</sup>.

## **1.2 Purpose**

To support acute hospitals to implement an Access, Watch and Reserve list of antimicrobials and provide information on pre- and post- authorisation of Reserve antimicrobials.

## **1.3 Scope of this policy**

### **1.3.1 Target users**

This policy is intended for use by antimicrobial stewardship teams in acute settings. It replaces the “National Policy on Restricted Antimicrobial Agents Health Service Executive” 2016.

### **1.3.2 Target population**

All patients that are prescribed antimicrobials in acute Irish hospitals.

## **1.4 Objective**

The objective of this document is to provide information to acute hospitals on the implementation of the WHO’s AWaRe criteria locally and outline the workflow for pre or post-authorisation of Reserve antimicrobials.

## 1.5 Outcomes

- All acute hospitals to implement the AWaRe classification of antimicrobials locally and to make the classification available to all staff as part of their empiric antimicrobial guidance.
- All acute hospitals to adopt the Reserve categorisation of antimicrobials as defined in this document.
- All acute hospitals to have a system of either pre or post-authorisation in place for Reserve agents.
- All acute hospital AMS teams to have a mechanism for regular review and audit of Reserve agent usage.

## 1.6 Disclosure of interests

The members of the development group have no conflicts of interest.

## 1.7 Rationale

This policy aligns to the “Antimicrobial Stewardship- Guidance for all Healthcare Settings 2022” which supports the approval and management of Reserve antimicrobials. In a 2013 update to a Cochrane review, meta-analysis of 52 interrupted time-series studies was used to compare restrictive versus purely persuasive interventions. Restrictive interventions had significantly greater impact on prescribing outcomes at one month (32%, 95% confidence interval (CI) 2% to 61%,  $P = 0.03$ ) and on microbial outcomes at 6 months (53%, 95% CI 31% to 75%,  $P = 0.001$ ). The meta-analysis supports the use of restrictive interventions when the need is urgent, but suggests that persuasive and restrictive interventions are equally effective after six months <sup>4, 5, 6</sup>.

## 1.8 Supporting evidence

The World Health Organization (WHO), Centre for Disease Control and the European Centre for Disease Prevention and Control (ECDC) all identify that infections with CPE are a serious threat to patient safety due to their resistance to

multiple antimicrobials, meaning that there are very few therapeutic options which to treat infected patients. Human infections with CPE are associated with poorer patient outcomes, increased morbidity, mortality (rates exceeding 40-50%) and higher hospital costs <sup>2</sup>.

There has been an increase in CPE surveillance and invasive CPE infections notified to public health since 2013 with 2020 and 2021 recognised as atypical years in healthcare in Ireland<sup>7</sup>. Development of new antimicrobial treatments is inadequate to address the mounting threat of antibiotic resistance, according to the annual pipeline report by the World Health Organization. The 2021 report describes the antibacterial clinical and preclinical pipeline as stagnant and far from meeting global needs. Since 2017 only 12 antibiotics have been approved, 10 of which belong to existing classes with established mechanisms of antimicrobial resistance (AMR) <sup>4</sup>. There is a recognised need to retain efficacy of agents currently available including carbapenems and newer combination agents.

## **1.9 Suggested citation**

Health Service Executive 2024, Reserve Antimicrobials Policy 2024.

## **1.10 Governance**

The HSE Reserve antimicrobial policy was commissioned by the HSE AMRIC Clinical Lead. The PPPG development group included the AMRIC acute services and AMRIC national team with consultation from the AMRIC AMS advisory group. The AMRIC national team recommended the HSE Reserve Antimicrobial Policy to the AMRIC clinical lead for final sign off.

This PPPG should be managed by the local AMS team at each site; these teams should be linked to the pharmacy/ drugs and therapeutics committee or quality and safety committee within the hospital.

## 2.0 Implementation plan

The clinical lead for AMS at each site should engage with the local AMS team to:

- Review the AWaRe categorisation proposed in this policy (Appendix 1)
- Review the Access and Watch categories and identify if any adjustments need to be made to this locally based on local outbreaks, local surveillance data and/or local medication safety issues
- The adapted AWaRe categorisation for the site should be readily accessible to all staff who prescribe, review and/or administer antimicrobials either via a local PPPG or as part of the local empiric antimicrobial guidance
- Review the current authorisation process for Reserve antimicrobials at the site and refer to section 2.2 of this document for direction on how to implement an authorisation process for Reserve antimicrobials at the site
- Communicate the new AWaRe categorisation to all relevant clinical stakeholders including clinical leads, prescribers, nursing and pharmacy
- Agree locally the procedure for prescribing and dispensing Reserve antimicrobials as per section 2.2
- Audit adherence to the prescribing and dispensing of Reserve antimicrobials as per this policy. This should take place quarterly as per section 2.4 and this should be undertaken by the AMS team
- A target of >90% adherence of Reserve antimicrobials dispensed as per policy is the target for the access to Reserve antimicrobials workflow (Appendix 2)
- Reserve agents should not routinely be ward stock; AMS teams should review stocklists and remove Reserve agents that are stock.

**The process for supply of Reserve agents must be designed so they do not delay prompt access to essential antimicrobial treatment for service users who need it.**



## **2.1 Procedure for prescribing and dispensing reserve antimicrobials**

The HSE published the, “Antimicrobial Stewardship Guidance for all healthcare settings” in August 2022 and defined two processes for authorisation:

- *Pre-authorisation approval process:* Each hospital should have a process in place to allow pre-authorisation for the use of Reserve antimicrobials by an infection specialist (microbiology or infectious disease consultant). Pre-authorisation may not be possible 24/7 where resources to support this are not available; in such cases, pre-authorisation should be in place during normal working hours with an alternative post-prescription authorisation in place out of hours (figure 1)
- *Post-prescription authorisation within 24-48hours (may extend to 72 hours for bank holidays)* – ‘Where pre-authorisation is not possible on a 24/7 basis, there should be a system for identifying when Reserve antimicrobials have been prescribed and early review of such prescriptions by an infection specialist (microbiology or infectious disease consultant) (figure 1).

**Processes for supply of Reserve agents must not delay prompt access to essential antimicrobial treatment for service users who need it.**

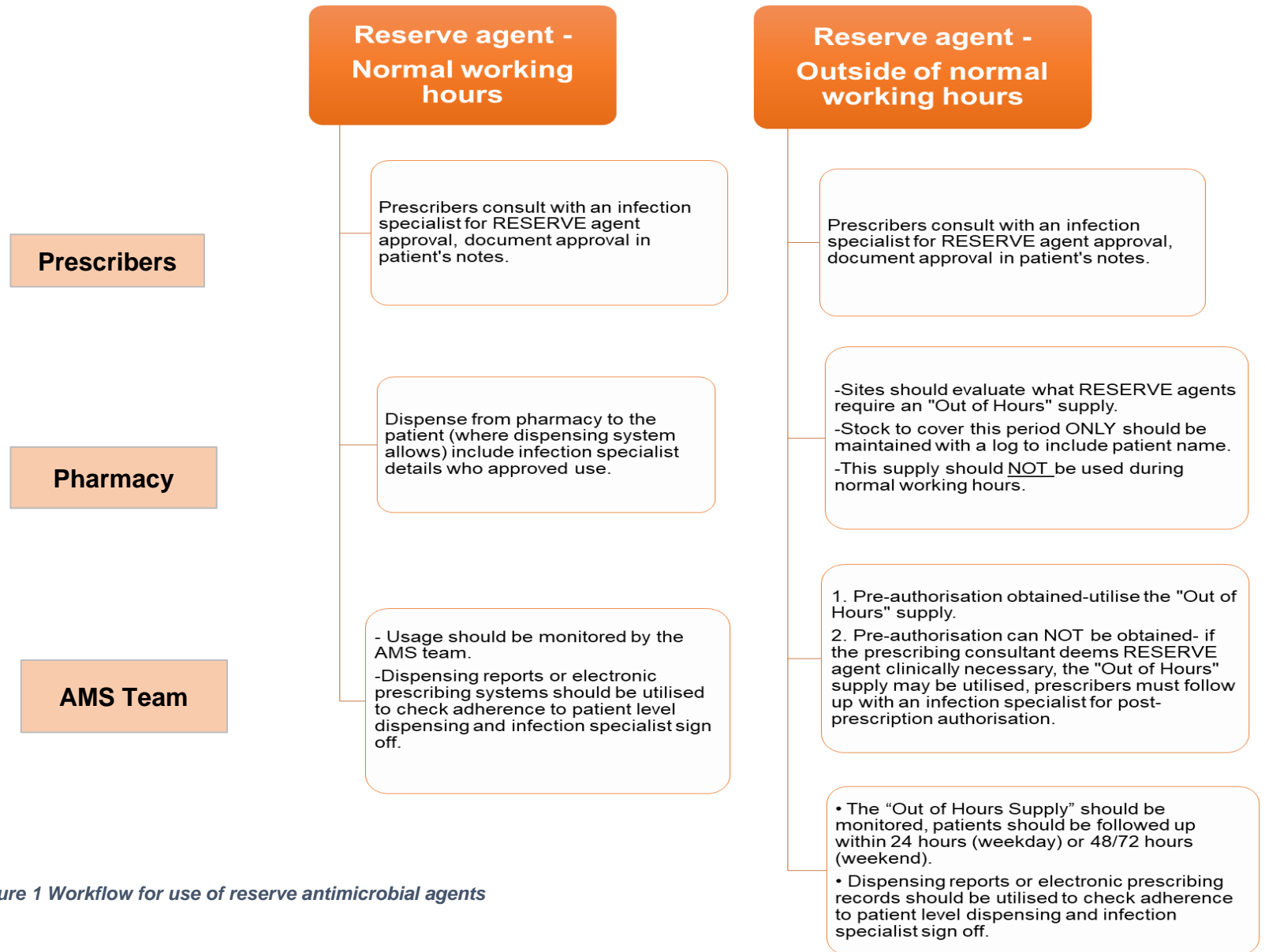


Figure 1 Workflow for use of reserve antimicrobial agents

## **2.2 Communication and dissemination**

It is the responsibility of the local AMS team to make all relevant clinical stakeholders at their site aware of the introduction of the AWaRe categorisation locally, specifically the introduction of the Reserve list of antimicrobials and the workflow for prescribing and dispensing of Reserve antimicrobials. The rationale behind the categorisation should be made clear to all stakeholders and the categorisation should be readily available to all staff either through a local PPPG or via local empiric antimicrobial guidance.

## **3.0 Sustainability**

### **3.1 Monitoring and evaluation**

The local AMS team has responsibility for monitoring adherence to the Reserve antimicrobial policy including follow up on Reserve antimicrobials used out of hours.

The Business Information Unit (BIU) collect healthcare associated infection (HCAI) data monthly from acute hospitals including the following questions:

- Does the hospital have a list of Reserve antimicrobials, which is in accordance with the HSE Reserve Antimicrobial Policy?
- Does the hospital have a process in place to ensure pre- or post- authorisation by a consultant in microbiology or infectious diseases, of the Reserve antimicrobial agents as per HSE Reserve policy 2024?

The following additional data should be collected and presented to AMS oversight/ drug & therapeutics committee and to regional level HCAI meetings:

- Reserve antimicrobial consumption as Defined Daily Doses/100 Bed Days used and as a proportion of total consumption
- Proportion of Reserve antimicrobials approved by infection specialist (microbiology or infectious disease consultant) either as part of a pre- authorisation workflow or post- authorisation workflow should be carried out quarterly (Appendix 2). A target of >90% of Reserve antimicrobials supplied should apply
- An audit of Reserve antimicrobial prescribing should be completed annually.

If there is usage of multiple Reserve agents and it is not possible to monitor all Reserve agents quarterly, the local AMS team should consider initially monitoring high priority antibiotics, for example carbapenems, and working towards expanding to Reserve antivirals and antifungals monitoring.

#### **4.0 Review and Update**

The next review date is December 16<sup>th</sup> 2027; amendments to the Access, Watch and Reserve antimicrobials list may be made in light of emerging evidence.

## 5.0 References

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3. Health Service Executive (2022). Antimicrobial stewardship guidance for all healthcare settings. <https://bit.ly/3o3vEyh>.
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7. Health Protection and Surveillance Centre 2023. Summary Report on Carbapenemase Producing Enterobacterales (CPE). April 2023.
8. 2021 Antibacterial agents in clinical and preclinical development: an overview and analysis. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

## 6.0 Glossary of terms

AMR	Antimicrobial Resistance
AMS	Antimicrobial Stewardship
AMRIC	Antimicrobial Resistance and Infection Control
AWaRe	Access Watch and Reserve
BIU	Business Information Unit
CPE	Carbapenemase Producing Enterobacterales
DDD	Defined Daily Doses
ECDC	European Centre for Disease Prevention and Control
HCAI	Health Care Associated Infection
HSE	Health Service Executive
IV	Intravenous
PPPG	Policy Procedure Protocol Guidance
WHO	World Health Organisation

## Appendix 1: AMRIC AWaRe categorisation

The WHO AWaRe categorisation has been adapted by AMRIC team to the categorisation in this document for consistency with the well-established green red categorisation in community settings, antimicrobials approved for use in the HSE, inclusion of antivirals & antifungals many of which are already Reserve agents in hospitals, and taking account of other national AMS work. Individual hospitals may decide due to local resistance data, local concerns pertaining to rates of *C difficile* and/or safety concerns that the Access or Watch categories may require local adjustment. The 3<sup>rd</sup> generation cephalosporins and/or the quinolones may be considered Reserve antimicrobial in some sites where *C difficile* rates are a concern.

<p><b>Access</b></p> <ul style="list-style-type: none"> <li>• Access antibiotics are antibiotics with a narrow spectrum of activity, generally with less side effects, a lower potential for the selection of antimicrobial resistance and of lower cost.</li> <li>• They are recommended for the empiric treatment of most common infections and should be widely available.</li> </ul>	<p>Aciclovir                  Amoxicillin                  Benzylpenicillin                  Cefazolin                  Cefalexin                  Chloramphenicol                  Doxycycline                  Famciclovir                  Fosfomycin (oral)                  Flucloxacillin                  Fluconazole                  Griseofulvin                  Itraconazole</p>	<p>Lymecycline                  Metronidazole IV/ oral                  Nitrofurantoin                  Phenoxymethylpenicillin                  Sulfamethoxazole/trimethoprim                  Terbinafine                  Trimethoprim                  Valaciclovir</p>
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<p><b>Watch</b></p> <ul style="list-style-type: none"> <li>• Watch antibiotics generally have a higher potential for the selection of antimicrobial resistance and are more commonly used in sicker patients in the hospital facility setting.</li> <li>• Their use should be carefully monitored to avoid overuse.</li> <li>• <b>**NOTE**</b> Third generation cephalosporins and/or the quinolones may be considered Reserve antimicrobial in some sites where <i>C difficile</i> rates are a concern-this should be evaluated locally</li> </ul>	<p>Liposomal amphotericin B (P)                  Amikacin                  Amoxicillin-clavulanic acid                  Anidulafungin (P)                  Caspofungin (P)                  Azithromycin                  Aztreonam                  Cefaclor                  Cefixime                  Cefotaxime                  Ceftazidime                  Ceftriaxone                  Cefuroxime                  Ciprofloxacin                  Clarithromycin                  Clindamycin</p>	<p>Erythromycin                  Fusidic-acid                  Gentamicin                  Vancomycin_IV                  Vancomycin_oral                  Levofloxacin                  Minocycline_oral                  Ofloxacin                  Posaconazole (P)                  Piperacillin / tazobactam                  Teicoplanin                  Temocillin                  Tobramycin                  Voriconazole (P)</p>
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(P) Prophylaxis- certain antifungals when used as prophylaxis in approved protocols may be considered Watch antimicrobials.

(T) Treatment- antifungals when used at treatment doses are considered Reserve antimicrobials.



<p><b>Reserve</b></p> <ul style="list-style-type: none"> <li>• Reserve antimicrobials are last-resort antimicrobials that should only be used to treat severe infections caused by multidrug-resistant pathogens.</li> <li>• These antimicrobials should be closely monitored and prioritized as targets of stewardship programs to ensure their continued effectiveness</li> <li>• Reserve antimicrobials should be prescribed in consultation with an infection specialist</li> </ul>	<p>Liposomal amphotericin B (T)                  Anidulafungin                  Caspofungin (T)                  Cefepime                  Cefiderocol                  Ceftaroline                  Ceftazidime / Avibactam                  Ceftolozane /Tazobactam                  Cidofovir                  Colistin IV                  Dalbavancin                  Daptomycin                  Delafloxacin                  Ertapenem</p>	<p>Fidaxomicin                  Flucytosine                  Fosfomycin IV                  Ganciclovir                  Isavuconazole                  Imipenem / Cilastatin                  Linezolid                  Meropenem / Vaborbactam                  Moxifloxacin                  Meropenem                  Minocycline IV                  Oritavancin                  Posaconazole (T)                  Rifampicin                  Streptomycin IV/PO                  Tigecycline                  Valganciclovir                  Voriconazole (T)</p>
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*Table 2 Access, Watch and Reserve categorisation of antimicrobials*

(P) Prophylaxis- certain antifungals when used as prophylaxis in approved protocols may be considered Watch antimicrobials.

(T) Treatment- antifungals when used at treatment doses are considered Reserve antimicrobials.

## Appendix 2: Monitoring and Evaluation

Hospital					
Implementation of local Reserve antimicrobial policy (Y/N)					
AWaRe classification available as part of the empiric antimicrobial guidance (Y/N)					
Year	Q1	Q2	Q3	Q4	Annual
No. of prescriptions dispensed for Reserve antimicrobials					
% of prescriptions for Reserve antimicrobials with infection specialist authorisation (either pre-or post-) <b>Target-&gt;90%</b>					

*Table 3 Monitoring and evaluation of Reserve antimicrobial policy*

### Appendix 3: Members of the AMRIC Oversight committee

<b>Members of the AMRIC Oversight committee</b>	
<b>Name</b>	<b>Role and position</b>
Dr Colm Henry	HSE Chief Clinical Officer
Dr Eimear Brannigan	National Clinical Lead, HSE AMRIC
Josephine Galway	Director of Nursing, HSE AMRIC
JP Nolan	HSE National Director/Head of Quality & Patient Safety
Liam Woods	HSE National Director, Acute Operations
Lorraine Doherty	National Clinical Director, Health Protection
Shirley Keane	Head of Service, HSE AMRIC
Siobhan Ni Bhriain	HSE National Lead Integrated Care
Yvonne O'Neill	HSE National Director Community Operations

## Appendix 4: Members of the AMRIC Advisory committee

Name	Role and position
Dr Eimear Brannigan	Clinical Lead, AMRIC (Chair)
Dr. Paul Ryan	GP AMRIC
Dr. Edel Doorley	GP Lead AMRIC
Umut Gurpinar	Epidemiologist, HSE - HPSC
Lauren Webster	Senior Epidemiologist, AMRIC
Dr Sinead O'Donnell	Consultant Microbiologist, Beaumont Hospital
Dr Alida Fe Talento	Consultant Microbiologist, CHI, ISCM representative
Prof Garry Courtney	National Clinical Lead for Acute Medicine
Dr Siad Ali	SpR Microbiology, NCHD representative
Mala Shah	Community Operations Representative, Chief II Antimicrobial Pharmacist, HSE Access & Integration - Quality & Patient Safety
Josephine Galway	Director of Nursing, AMRIC
Dr. Anne O'Neill	National Clinical Lead for Oral Health
Marie Philbin	Chief I Antimicrobial Pharmacist, AMRIC
Ellen Martin	Senior Antimicrobial Pharmacist, AMRIC
Dr. Scott Walkin	ICGP AMRIC Lead
Dr David Hanlon	National Clinical Advisor and Group Lead for Primary Care
Mary Kelly	Chief II, Antimicrobial Pharmacist, HSE Access and Integration
Dr Gerard McCarthy	National Clinical Lead for Emergency Medicine
Ruth Hoban	HSE West, Assistant Director of Nursing and Midwifery (Prescribing), ONMSD representative
Prof. John Murphy / Dr. Ellen Crushell	National Clinical Lead for Paediatrics
Sarah Clarke	Medicines Management Programme representative
Dr Niamh O'Sullivan	Chair of Antimicrobial Susceptibility Testing Group (subgroup of ISCM)
Fiona Leonard	Community pharmacist (nominee from community pharmacy contingency group)
Dr Margaret McGloughlin	GP representative with RCF perspective
Professor Colm Bergin	Clinical Lead, Infectious Diseases
Dr Geraldine Moloney	Consultant in Infectious Diseases & IDSI rep
Dr Stanley Millar	Clinical Lead for Respiratory
Nina Acosta	Senior Pharmacist, AIDMP
Ciara Hughes	Programme Manager National Clinical Programme for Surgery (or National Clinical Lead for Surgery)
Dr. Eavan Muldoon	Consultant in Infectious Diseases, OPAT


## Appendix 5: Members of the Policy Development Group

Name	Role and Position
Mary Kelly	Chief II, Antimicrobial Pharmacist, HSE Access and Integration
Marie Philbin	Chief I Antimicrobial Pharmacist, AMRIC
Ellen Martin	Senior Antimicrobial Pharmacist, AMRIC

## Appendix 6: Members of HSE AMRIC Acute Guidance Governance Group

HSE Reserve antimicrobial Policy was formally ratified and recorded in the minutes of the HSE AMRIC acute guidance approval meeting on December 16<sup>th</sup> 2024.

Membership of Policy Approval Group	
Name	Role and Position
Dr Eimear Brannigan	Clinical Lead, AMRIC
Mary Kelly	Chief II, Antimicrobial Pharmacist, HSE Access and Integration
Marie Philbin	Chief I Antimicrobial Pharmacist, AMRIC
Therese Dalchan	Head of Service, AMRIC Acute Services, Office of Director of Access and Integration HSE

<b>Name: (print)</b>	Dr Eimear Brannigan
<b>Title:</b>	HSE AMRIC Clinical lead
<b>Signature:</b> <b>(e-signatures accepted)</b>	
<b>Registration number:</b> (if applicable)	IMC 022539