TABLA 1

FINAL CONSENSUS ON THE CHARACTERIZATION OF THE P&R CRITERIA LISTED IN THE RDL 1/2015. FOR EACH CRITERION, THE AGREED SUBCRITERIA AND ITS DEFINITIONS ARE SHOWN

Criteria	**A.**	**Severity, duration, and after-effects of the different pathologies for which they are indicated**
Subcriteria definition	A.1	Disease description: Description of the affected population and patient subgroup (including prevalence and incidence), etiology, disease duration, symptoms, associated risk factors, and disease progression.
	A.2	Impact of the disease on mortality: Defined by the mortality rate and the years of life lost due to premature death.
	A.3	Impact of the disease on morbidity: Description of the associated diseases that characterize the population group affected by the disease.
	A.4	Impact of the disease on the patient's quality of life: Defined by the changes it produces in the symptoms, and physical, psychological, cognitive, or general social function of the patient.
	A.5	Impact on the quality of life of family members/caregivers: Defined by the changes it produces in the symptoms, and physical, psychological, cognitive, or social function of the patient's caregivers or relatives.
Criteria	**B.**	**Specific needs of certain groups**
Subcriteria definition	B.1	Unmet needs in efficacy : There is no availability of effective therapeutic alternatives or standard of treatment that covers the needs for efficacy for recovery from disease, increased survival, morbidity, and long-term improvement of severe symptoms
	B.2	Unmet needs in safety: there is no availability of effective therapeutic alternatives or standard of treatment that covers the needs for safety regarding direct and indirect adverse events of the drug for patients, their frequency, severity or subgroups of greater susceptibility
	B.3	Unmet needs in patient's quality of life: The available therapeutic alternatives do not improve the health-related quality of life or reduce the social impact of the disease on the patient and their caregivers
Criteria	**C.1**	**Therapeutic value of the drug**
Subcriteria definition	C.1.1	Effect of the drug on mortality: the drug can cure the disease or significantly modify the clinical course of the disease.
	C.1.2	Effect of the drug on morbidity: The drug can improve the set of associated disease that characterize the population group affected by the disease.
	C.1.3	Effect of the drug on patient's health-related quality of life: The drug can improve the symptoms, the physical and psychological, cognitive, or social function of the patient and specific of the disease.
	C.1.4	Effect of the drug on the caregivers' quality of life: The drug can improve the symptoms, physical and psychological, cognitive, or general social function of the caregivers or relatives of the patient.
	C.1.5	Effect of the drug on patient safety: Direct and indirect adverse events of the drug for patients, their frequency, severity, or subgroups of higher susceptibility.
	C.1.6	Effect of the drug on patient satisfaction and preferences: It defines nonmedical outcomes reported by the patient on the use of the drug, includes degree of satisfaction, preference, or acceptability of the drug.
	C.1.7	Therapeutic positioning: Place that the drug occupies within the therapeutic scheme of the disease. For example: first line of the treatment or "add on" therapy.
	C.1.8	Type of benefit provided by the drug: It includes prevention, treatment of symptoms, modification of the clinical course or cure of the disease.
Criteria	**C.2.**	**Social value of the drug and its incremental clinical benefit, considering its cost-effectiveness ratio**
Subcriteria definition	C.2.1	Incremental clinical efficacy/effectiveness: Identification and indication of differential aspects between the evaluated drug and the intervention/s of the usual clinical practice in terms of efficacy and/or effectiveness. The magnitude of the comparative clinical benefit, the size of the benefited population by the benefit, the onset and duration of the health improvement, and other relevant health outcomes for the specific therapeutic area are included.
	C.2.2	Incremental safety and tolerability: Identification and indication of differential aspects between the evaluated drug and the intervention/s of usual clinical practice in safety. Comparisons of adverse events, serious adverse events, fatal adverse events, short- and long-term safety, and tolerability are included.
	C.2.3	Health-related quality of life: It defines the health-related quality of life outcomes compared to the usual clinical practice intervention/s. It includes improvement in the quality of life related to health, impact on autonomy, impact on dignity, convenience, ease of use, administration mode and instructions.
	C.2.4	Incremental cost of the intervention: It defines the cost of the intervention in comparison with the intervention/s of usual clinical practice. The comparison includes the net cost of the intervention between the drug and comparators, the acquisition costs, and the maintenance and/or implementation costs.
	C.2.5	Incremental direct costs (healthcare costs): It defines the cost of the intervention in other medical costs such as hospitalization, specialist consultation, cost of adverse events and attendance.
	C.2.6	Incremental indirect costs (nonhealthcare costs): Defines the impact of the intervention on nonmedical costs such as disability, social services, productivity losses or caregivers. The comparison includes the impact on productivity, the financial impact on patients, the financial impact on caregivers, and costs on social services.
Criteria	**D.**	**Rationalization of public spending for pharmaceutical services and budget impact on the National Health System**
Subcriteria definition	D.1	Size of the target population: Proportion of patients who can receive the new drug, including previously untreated patients. It is required to quantify the degree of penetration at 3 years according to objective criteria.
	D.2	Use of resources: Identification, quantification and evaluation of the resources consumed in health services of the intervention in comparison with the intervention of habitual practice (comparator/s). The perspective used is from Spanish National Health System.
	D.3	Incremental cost of the intervention: It defines the cost of the intervention in comparison with the intervention/s of the usual clinical practice. The comparison includes the net cost of the intervention between the drug and comparators, the acquisition costs and the maintenance and/or implementation costs.
	D.4	Incremental direct costs: It defines the cost of the intervention in other medical costs such as hospitalization, specialist consultation, cost of adverse events and attendance. Comparison includes primary care costs, hospital care costs, and long-term care expenditures.
Criteria	**E.**	**Existence of drugs or other therapeutic alternatives for the same conditions at a lower price or lower cost of treatment**
Subcriteria definition	E.1	Alternative treatments: Existence of drugs or treatments in Spain for the specific health problem. All relevant interventions from usual clinical practice should be included. It should describe the differential aspects of the interventions, including posology, frequency, and method administration, use in combination with other interventions, use in sequence with other interventions, location along the treatment or care scheme, and any relevant initial/stop rules.
	E.2	Incremental cost of the intervention: It defines the cost of the intervention in comparison with the intervention/s of the usual clinical practice. The comparison includes the net cost of the intervention between the drug and comparators, the acquisition costs, and the maintenance and/or implementation costs.
Criteria	**F.**	**Degree of innovation of the drug**
Subcriteria definition	F.1	Drug innovation in the method of administration: Defined as an administration method that favors the comfort of the patient with the treatment compared to the standard of treatment.
	F.2	Drug innovation in the posology and duration of treatment: Defined as an improvement in the posology or a decrease in the duration of treatment compared to the standard of treatment.
	F.3	Drug innovation in the mechanism of action: Defined as an alternative in the mechanism of action of the drug compared to the standard of treatment.
	F.4	Drug innovation in the molecular entity: Defined as a new molecule or formulation for treatment versus standard of treatment.
	F.5	Technological innovation of the drug: Defined by changes in the drug that have a positive impact on its use and/or for the patient. Including new or sensible improvements in the device or in the presentation.

Fuente: Calleja MÁ, Badia X (2022). Feasibility study to characterize price and reimbursement decision-making criteria for the inclusion of new drugs in the Spanish National Health System: the cefiderocol example. International Journal of Technology Assessment in Health Care.