

Healthcare services requiring prior authorisation

List based on the Directive 2011/24/EU of 2013.

Article 8 (2 a) healthcare subject to prior authorisation

- i. Involves overnight hospital stay for one night or more;
- ii. Healthcare involves the use of highly specialised and cost-intensive medical infrastructure or medical equipment;

Article 8 (2 b) healthcare that involves treatments presenting a particular risk for the patient or population

Article 8 (2 c) healthcare that is considered to provide a serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

Article 8 (6) healthcare where prior authorisation may be refused

Article 8 (6 a) healthcare that with reasonable certainty will present a patient-safety risk that is not acceptable;

Article 8 (6 b) healthcare where the general public will be exposed with reasonable certainty to a substantial safety hazard

Article 8(6 c) healthcare that raises serious and specific concerns related to standards and guidelines on quality of care and patient safety

The list does not include:

- a) long-term care and services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks (Article 14).
- b) organ transplants (Article 15)

The service/s requiring prior authorisation must form part of the National Healthcare Package of Malta.

The list may be updated from time to time.

Prior authorisation list	
The following are the services subject to prior authorisation (all services are classified according to the <u>Maltese</u> healthcare package)	
All healthcare services that require an overnight stay for one night or more	
Specialised services that require the use of complex and cost-intensive medical infrastructure	Procedures under this category may include:
	CT scan & Magnetic Resonance Imaging
	CT diagnostic & therapeutic radiology
	Radiologically guided interventions ¹
	Nuclear Medicine
	Radiofrequency Ablation
Other services requiring use of complex and cost-intensive medical infrastructure ²	
Gynaecological and Obstetric services	Specialist services including assisted reproductive technology including IVF
Genetic services	
Hyperbaric medical services	
Cancer treatment	Specialist services including specialised treatments & radiotherapy services
Rare diseases	Specialist services required for rare conditions (as defined by [ORPHANET])
The following are the services that fall outside the scope of the Directive and consequently the Directive does not apply	
Long-term care (such as nursing homes, rehabilitation care and palliative care)	
Treatment that is in its trial or experimental phase	
Public vaccination programmes	

¹ Radiological guided interventions include: Arteriography, Phlebography, Angioplasty, Angiography, Vascular, Percutaneous Coronary Interventions (PCI), Transcatheter Aortic Valve Interventions, Percutaneous Mitral Valve interventions, Endoscopic Retrograde Cholangiopancreatography (ERCP), Percutaneous Nephrolithotomy (PCNL)

² Such as ECT, cochlear implants