

# 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.

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

<sup>1</sup> 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)

<sup>2</sup>Such as ECT, cochlear implants