Guidelines to be followed by centres, services and units in order to be designated as Reference Centres, Services and Units of the National Health System. as agreed by the Interterritorial Board

14. INTENSIVE CHEMOTHERAPY TREATMENT OF GERM CELL TUMOURS

Focus on the treatment of patients with germ cell tumours occurring on any site (gonadal and extragonadal) with recurrence after chemotherapy treatment and who must be assessed from a multidisciplinary perspective in a specialized reference centre, in order to assess indication for intensive chemotherapy (with hematopoietic support).
It involves patients who, after recurrence, are susceptible to chemotherapy and/or radiotherapy treatments, reaching 90% recoveries. Indication or assessment of intensive chemotherapy would be in a much reduced subgroup of patients with spread disease who, after assessing response to first- and second-line chemotherapy, have a recurrence. For cases of chemosensitivity, the option to this treatment must be assessed.

A. *Rationale for the proposal*

► Epidemiological data on germ cell tumours (incidence and prevalence).	In Spain, there is an estimated annual incidence of 820 germ cell tumours. 40% of the cases are seminomas, and the rest are related to nonseminomatous germ cell tumours (data from the Spanish germ cell cancer cooperative group).
► Data on the use of the technique.	55% of the nonseminomatous tumours and 25% of the seminomas appear in advance stages (III-IV). From these cases, 15% will have a recurrence after first-line chemotherapy. Cases with recurrences are treated with second-line chemotherapy. From cases treated with second-line chemotherapy, 20-25% will recover whereas the rest will progress and be susceptible to intensive chemotherapy. Applying these percentages to the estimated incidence, it is presume that 25 to 40 patients in a year are candidates to assess third-lines of chemotherapy with possible indication of intensive chemotherapy. Thus, indication for treatment with intensive chemotherapy in Spain is estimated for a maximum of 30 cases per year.

B. ***Guidelines to be followed by Centres, Services and Units in order to be designated as Reference Centres, Services and Units treating germ cell tumours with intensive chemotherapy.***

► Experience of the Reference Centres, Services and Units: - Activity:	
• Number of intensive chemotherapies (minimum and optimal) that should be performed in a year to ensure an adequate care.	Annual minimum of 5 new cases of germ cell tumours (or more than 15 in the last 5 years) with indication of third-line chemotherapy.
• Number of procedures (minimum and optimal) that should be performed in a year of techniques, technologies and procedures similar to those specific to the designation requested.	Therapeutic decision assessed through a multidisciplinary team with experience of more than 5-10 cases of germ cell tumours treatments in a year.
- Other data: research on the subject, postgraduate teaching, continuing training, etc.	▪ Accredited postgraduate teaching. ▪ Participation in research projects (national or international cooperative research group on germ cell tumours) and publications in the field[a]. ▪ Continuing training programme[a].

► Specific resources of the Reference Centres, Services and Units: - Human resources required for the adequate implementation of the procedure. Professional experience[b]**.** - Specific equipment required for the adequate implementation of the procedure. ► Resources from other units and services besides those belonging to the Reference Centres, Services and Units required for the adequate care of the pathology or implementation of the procedure.	Existence of a Hospital tumour board with an updated action protocol based on scientific evidence. • Multidisciplinary team including: medical oncologist in charge of the pathology, clinical oncologist, urologist and haematologist, as well as medical and surgical specialists as needed. ▪ Medical oncologist and haematologist with 5 year experience in intensive chemotherapy with hematopoietic progenitor-cell support and in relapsed germ cell tumours. ▪ Urological surgeons with experience in surgical treatment of these patients. ▪ Clinical oncologists with 5 year experience in diagnosis and treatment of these patients. ▪ Equipment expected in a hematopoietic progenitor-cell transplantation unit, with the possibility to perform autologous transplantations. ▪ Unit for harvesting, processing, preservation and infusion of hematopoietic cells in order to implement cell apheresis and infusion techniques. ▪ Pathologic anatomy with anatomical pathologists with 5 year experience in diagnosis[b]. ▪ Surgical teams with experience in retroperitoneum, lung and mediastinum surgery[b], for resection of post-chemotherapy residual masses. ▪ Intensive care. ▪ Image diagnosis. ▪ Microbiology.
► Procedure and clinical results indicators of the Reference Centres, Services and Units [c]:	**The indicators will be agreed with the Units that will be designated.**
► Existence of an adequate IT system (Type of data that the IT system must include to allow identification of the activity and evaluation of the quality of the services provided)	▪ Filling up the complete MBDS of hospital discharge. ▪ Besides, the unit must have a *registry of patients* who have undergone intensive chemotherapy, which at least must include: - Data required for the tumour registry of the hospital[1]: patient's identity (medical record

	number), date of birth, sex, address, tumour site (International Classification of Diseases for Oncology[2]), date of diagnosis and recurrence, diagnosis method, tumour histology, stage. If applicable, cause and date of death. - Initial diagnosis (ICD-9-CM), diagnosis date. - Initial treatment and date of initial treatment, response assessment. - Recurrence, recurrence date. - Admission date and discharge date. - Date of intensive chemotherapy. - Other procedures performed (indicate ICD-9-CM) and additional chemotherapies (date, type of chemotherapy, and response assessment), intensive therapy technique or guidelines, and hematopoietic progenitor-cell support if applicable, annual follow-up of vital status. - Complications. In the event of consultation about therapeutic decision resulting in the non-prescription of intensive therapy, the same information must be included. - The unit must have the required data which should be sent to the Spanish National Health Service Reference Centres, Services and Units Appointment Commission Secretariat for yearly reference unit monitoring.

[a] *Criteria to be assessed by the Appointment Commission.*
[b] *Experience will be accredited by certification from the hospital manager.*
[c] *Clinical results standards, agreed to by the experts group, will be assessed, initially by the Appointment Commission, while in the qualification process, as more information from the Reference Centres, Services and Units is being obtained. Once qualified by the Appointment Commission, the Quality Agency will authorize its compliance, as for the rest of guidelines.*

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[1] Jensen OM, Parkin DM, Maclennan R, Muir CS, Skeet RG (eds). Cancer Registration Principles and Methods. Lyon**:** IARC Scientific Publications Nº 95, 1991.

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