Guidance - Checklist

A. Description of the disease	
1	Enter the name and a brief description of the disease, e.g., natural progression, pathophysiology, etc.
2	State incidence and/or prevalence NB. In Sweden, rarity is classified according to the following scale: Common condition – More than 200 patients Less common condition – At most 200 patients in Sweden Rare condition – At most 50 patients in Sweden Very rare condition – At most 10 patients in Sweden
3	State e.g., duration, chronic, progression
4	Add previous classification by TLV/NT-council is an assessment has been made. NB. In Sweden disease severity is graded on the following scale: Low – Discomforting but not painful. No effect on survival. Moderate – Debilitating or with survival effects in the long run. High – Life threatening in the short-term or mid-term, alternatively severely debilitating. Very high – Immediately life threatening and/or painful condition.
5	Specify existing treatment options (according to established guidelines)
B. Clinical evidence	
1	State clinically relevant outcome measure (primary and secondary), e.g., overall survival (OS) benefit, improved quality of life (QoL), improvement on a six-minute walk test (6MWT) etc.
1.1	State surrogate measures. Is the measure validated?
2	Describe how the clinical effectiveness is determined, e.g., head-to head randomized clinical trials, indirect comparisons.
3	Is a matched historical cohort used?
4	Describe clinically meaningful consequences and probabilities
5	State the number of patients
6	State duration (months/years)
C. Health economic evidence	
1	Describe the value to the health care system
2	Describe the potential for cure
3	Are there other treatment options= How are patients treated today? Competition?
4	State comparator or treatment option, e.g., an active comparator or standard of care. NB. The comparator can differ between countries and subgroups.
5	What is the benefit compared to the comparator?
6	What is the benefit compared to the comparator?
7	Describe relevant costs, both direct and indirect.
8	Describe the relevant population to be treated and possible subgroups.
9	State the perspective of the analysis, typically either a societal or health care payer perspective.
10	Specify what type of model should be used and the most suitable type of analysis, e.g., cost-effectiveness analysis, cost-minimization analysis.
11	State the time horizon for the model and how long-term effects are to be extrapolated.

	NB. The time horizon should encompass the period where the main health effects and costs occur.
12	State resources saved (and relevant cost savings) and where these occur.
13	State the discount rate used for costs and health effects.
14	Report sensitivity analyses (and the methods used for these) and the main drivers of uncertainty around the results (e.g., price, OS benefit)
D. Budget impact, payment and risk sharing	
1	State the number of patients eligible for treatment year by year and what costs and savings are expected.
2	State how a new payment model may reduce the budget barrier and how risk sharing is used to reduce uncertainty around effects and costs.