|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ATMP Checklist  The proposed checklist has been developed taking international health economic recommendations and existing health economic guidelines and decision-making processes for the introduction of new pharmaceuticals in Sweden (Drummond et al., 2019; NT-Rådet, 2019; TLV, 2017). The list is a guidance and aims to support integrated thinking around the generation, synthesis, and presentation of evidence throughout the commercialization process of an ATMP. Refer to the attached guidance for instructions of how to complete the checklist. | | | | | | | |
| 1. Description of the disease | | | | | | | |
| No. | **Object** | **Information/Comments** | | | | | |
| 1 | Disease |  | | | | | |
| 2 | Rarity of the condition |  | | | | | |
| 3 | Duration of the condition |  | | | | | |
| 4 | Severity of the condition |  | | | | | |
| 5 | Current treatment |  | | | | | |
| B. Clinical evidence | | | | | | | |
| No. | **Object** | **Yes** | **No** | **Information/Comment** | | | |
| 1 | Selection of outcome measure |  |  |  | | | |
| 1.1 | Use of surrogate measures |  |  |  | | | |
| 2 | Direct comparison |  |  |  | | | |
| 3 | Single arm study |  |  |  | | | |
| 4 | Adverse events, consequences, and risks |  |  |  | | | |
| 5 | Size of clinical trial |  | | | | | |
| 6 | Duration of clinical trial |  | | | | | |
| 1. Health economic evidence | | | | | | | |
| No. | **Object** | **Yes** | **No** | **Comment** | | | |
| 1 | Value to the health care provider |  |  |  | | | |
| 2 | Potential of cure |  |  |  | | | |
| 3 | Lack of treatment options |  |  |  | | | |
| 4 | Comparator |  | | | | | |
| 5 | Survival benefit |  | | | | | |
| 6 | Improved quality of life |  | | | | | |
| 7 | Care process and resource use |  | | | | | |
| 8 | Target population |  | | | | | |
| 9 | Study perspective |  | | | | | |
| 10 | Analytical method |  | | | | | |
| 11 | Time horizon |  | | | | | |
| 12 | Saved resources |  | | | | | |
| 13 | Discounting |  | | | | | |
| 14 | Uncertainty |  | | | | | |
| D. Budget impact, payment, and risk sharing | | | | | | | |
| No. | **Object** | **Information/Comment** | | | | | |
| 1 | Affordability |  | | Year | | | |
|  | | 1 | 2 | 3 | +4 |
| Number of patients | |  |  |  |  |
| Costs | |  |  |  |  |
| Savings | |  |  |  |  |
| 2 | Innovative payment model |  | | | | | |

**References**

Drummond, Michael F. et al. (2019). Analytic Considerations in Applying a General Economic Evaluation Reference Case to Gene Therapy.Value in Health, Volume 22, Issue 6, 661 – 668.

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Tandvårds- och läkemedelsförmånsverkets (TLV). (2017). Ändring i Tandvårds- och läkemedelsförmånsverkets allmänna råd (TLVAR 2003:2) om ekonomiska utvärderingar; beslutade den 26 januari 2017. TLVAR 2017:1 [hämtad 2020-05-20 https://www.tlv.se/download/18.467926b615d084471ac3230c/1510316374332/TLVAR\_2017\_1.pdf]