Scope of vignette:
- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- submissions for P&R made by manufacturers

Green = related to/any special considerations for OMPs/UOMPs

France	**Standard HTA process**	**Accelerated procedure**	**Fast-track**	**ATU**
Overview of health system	Tax based health system [5] The Ministry of Social Affairs, Health and Women's Rights is responsible for defining national strategy. The central government allocates budgets to the different sectors (hospital, ambulatory, mental health, services for disabled). The MoH is represented in the regions by the regional health agencies, which are responsible for population health and healthcare [5]. The Haute Autorite de Sante (HAS) is an independent public scientific agency and is an advisory HTA body to the MoH. It is in charge of HTA.			
Overview of health system and P&R/HTA process	After marketing authorisation, HAS conducts HTA to determine if medicine is to be included on a positive list of reimbursed products. Assessment is based on medical evidence.	Accelerated product assessment.	Allows a very early submission, as soon as the request for MA is submitted and at any time before positive opinion of EMA's Committee for Medicinal Products for Human Use (CHMP)	Temporary early access (ATU) to medicines (before marketing authorisation[6]) granted by the French Medicines Agency (ANSM): - Cohort ATU - Nominative ATU
Differentiation of rare disease treatments in the P&R system	None			
Eligible medicines	All drugs	Medicines authorised by a centralised procedure or a mutual recognition, including medicines for rare diseases.	1. New mode of action, 2. fulfils an unmet need, and 3. data available suggests clinically relevant progress (efficacy, safety, access to the therapy)	1. Fulfils an unmet need without any other alternative 2. Data available suggests a positive risk balance 3. Treating a rare or severe disorder [6]

France	Standard HTA process	Accelerated procedure	Fast-track	ATU
				* After MA is granted, drugs with ATU cannot be candidates for fast track/accelerated procedure.
Process	- Manufacturer submits an application to HAS. - - Assessment is performed by HAS (submission, literature, write up of report). - Appraisal by Transparency Committee (TC) based on submission and expert opinions - Opinion sent to manufacturer, who can respond in writing or request a hearing - Final opinion sent to National Health Insurance Funds (Uncam), Economic Committee of Healthcare Products (CEPS) to determine level of co-payment and pricing, respectively. The final decision for inclusion is taken by the MoH [4]	- Application to HAS may be sent as soon as the CHMP of EMA has given a favourable opinion for MA (for centralised procedure) or as soon as the summary of product characteristics is available (for mutual recognition) - The assessment by HAS can start, but the TC opinion will be given only when marketing authorization is granted	- Application to HAS may be sent as soon as the request for MA is submitted - The assessment by HAS can start ,but the TC opinion will be given only when marketing authorization is granted	
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	- Disease-specific clinical experts and patient associations[1] are invited to provide input on the assessment - For rare diseases, clinical experts are involved in the assessment of the drug. They help the TC with their knowledge about the rare disease and clinical data. The clinical experts must be independent, without connection to the pharmaceutical company in charge of the assessed product or those in charge of the comparator. In a few cases, in conformity with the “charte			

[1] https://www.has-sante.fr/portail/jcms/c_2666630/fr/contribution-des-associations-de-patients-et-d-usagers-aux-evaluations-de-medicaments-et-dispositifs-medicaux

France	Standard HTA process	Accelerated procedure	Fast-track	ATU
	de déontologie[2]" of HAS, the TC can accept to work with an expert which has such a connection			
Key domains in assessment	- Clinical benefit, clinical added value			
Evidentiary requirements	For RDTs, evidentiary requirements are the same as for the standard process, but HAS considers context and feasibility of performing RCTs and comparisons to an active comparator or placebo or to best supportive care. A demonstration with a substantial effect size with a validated endpoint and at least historical cohort data to describe the natural history of the disease should be provided. The choice of a single arm, non-randomised study has to be very well justified. HAS also often asks for additional data based on registries for rare diseases (post HTA).			
PROMs	Quality of life data [3]			
Appraisal framework	Transparency committee [1] appraisal is based on: - Clinical benefit (service médical rendu, SMR) informing reimbursement and co-payment - Clinical added value (amélioration du service médical rendu, ASMR) informing pricing [2] * The unmet medical need in rare disease may impact the level of clinical added benefit, but it is not the only criteria taken into account for the appraisal of the clinical added benefit[3]			
Reimbursement decision	SMR level informs reimbursement level and co-pay ASMR level informs the pricing scheme applicable			
Pricing process	Price is determined by Ministry of Health based on the HAS appraisal [2] ASMR I-III: price negotiation (price premium) ASMR IV-V: price same or lower than comparator			
Managed entry agreements	None			

[2] https://www.has-sante.fr/portail/upload/docs/application/pdf/2010-06/charte_deontologie_has.pdf
[3] https://www.has-sante.fr/portail/upload/docs/application/pdf/2018-10/doctrine_10102018.pdf

France	Standard HTA process	Accelerated procedure	Fast-track	ATU
Main challenges in appraising medicines for rare diseases (tick all that apply)	X Lack of good quality clinical data X Lack of real world data X Introducing value for money (applies for authorities in charge of pricing assessment) X Monitoring treatment efficacy X Managing budget impact (applies for authorities in charge of pricing assessment) X Lack of criteria/transparency of OMP P&R processes ☐ Making arrangements to work for all stakeholders X Lack of long-term meaningful outcomes ☐ Other, please specify			
Impact of special processes				
Proposed policy change	In July 2018, the government communicated on the importance of rapid access to the patient of innovative drugs. It underlined the importance of respecting the timeline for assessment of the medicine. It announced the modification of the two scores SMR and ASMR in a unique score named VTR or "valeur thérapeutique relative" planned for the coming years			
Joint initiatives	EUnetHTA			
Sources				
1	https://www.has-sante.fr/portail/jcms/c_1729421/en/transparency-committee			
2	https://www.has-sante.fr/portail/jcms/c_2035651/en/methods-and-criteria-for-assessing-medicinal-products			
3	Dossier Type, premiere inscription ou extension d'un medicament, HAS, Commission de la Transparence, v 27 aout 2018			
4	https://www.has-sante.fr/portail/upload/docs/application/pdf/2014-03/commission_transparence_2014_v4.pdf			
5	https://international.commonwealthfund.org/countries/france/			
6	https://ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/Qu-est-ce-qu-une-autorisation-temporaire-d-utilisation/(offset)/0			

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This vignette was compiled based on information provided by country experts and desk research. The information provided may be incomplete or contain inaccuracies. If you have any comments or updates, please email us at the following email addresses:

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