

# UNA NEWSLETTER SULLE AGENZIE DI HTA

## Benchmarking delle decisioni sull'accesso ai farmaci

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### Introduzione

Nel governo dei sistemi sanitari, la valutazione delle tecnologie sanitarie (HTA) svolge un ruolo chiave. Le Agenzie di HTA (A-HTA) utilizzano metodi espliciti per definire il valore di una data tecnologia, a supporto del processo decisionale. I pareri espressi dalle diverse A-HTA consentono di effettuare un benchmarking delle decisioni assunte, particolarmente utile per regolatori e operatori sanitari. Sono state selezionate sei tra le più importanti A-HTA a livello internazionale per un monitoraggio mensile dei report prodotti da queste ultime sui farmaci.

### Obiettivo

Descrivere uno strumento informativo che, mensilmente, sintetizza i pareri relativi a rimborsabilità e costi di nuove entità chimiche (NCE) e nuove indicazioni (NI), valutati da sei A-HTA.

### Metodi

Canada => **CADTH**    Scozia => **SMC**

Francia => **HAS**    U.S.A. => **ICER**  
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Germania => **IQWiG**    U.K. => **NICE**

SMC							
Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences	data
antitrombotico	Dapagat	For the treatment of acute thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.	Medicine advice	<a href="https://www.cadth.ca/medicines-at/antitrombotico-dapagat">https://www.cadth.ca/medicines-at/antitrombotico-dapagat</a>	is accepted for use within the jurisdiction.	In two phase II studies in patients with chronic liver disease who were scheduled to undergo an invasive procedure, dapagat was superior to placebo for the proportion of patients who did not require a platelet transfusion or any rescue procedure for bleeding after randomisation and up to 7 days following the procedure.	07.12.2021
medicina	Namenda	Symptomatic treatment of myasthenia in adult patients with non-thymic myasthenic disorders.	Medicine advice	<a href="https://www.cadth.ca/medicines-at/namenda">https://www.cadth.ca/medicines-at/namenda</a>	is accepted for use within the jurisdiction.	In a short-term, phase II, crossover study, meclidine significantly improved muscle stiffness compared with placebo when measured on a visual analogue scale. This advice applies only in the context of an approved Medication Review Access Scheme (MRAS) arrangement following the cost-effectiveness results upon which the decision was based, or a HAQ for price that is equivalent or lower. The advice takes account of views from a Patient and Clinician Engagement (PAC) meeting.	07.12.2021
anticoagulante	Verzenio	In combination with abiraterone (ABC) is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).	Medicine advice	<a href="https://www.cadth.ca/medicines-at/verzenio">https://www.cadth.ca/medicines-at/verzenio</a>	is accepted for restricted use within the jurisdiction.	Verzenio (abiraterone), compared with abiraterone (abiraterone), significantly improved progression-free survival in adult patients with CLL and no relapsed SMC. SMC includes the use of (1) patients without del(17p) mutation who are not fit to receive FCR (fludarabine, cyclophosphamide and rituximab) chemotherapy and (2) patients with del(17p) mutation. This advice applies only in the context of an approved Medication Review Access Scheme (MRAS) arrangement following the cost-effectiveness results upon which the decision was based, or a HAQ for price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PAC) meeting.	07.12.2021
benzodiazepinico	Nelondo	In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.	Medicine advice	<a href="https://www.cadth.ca/medicines-at/nelondo">https://www.cadth.ca/medicines-at/nelondo</a>	is not recommended for use within the jurisdiction.	In four phase III studies, the percentage reduction in LDL-C in 12 weeks was significantly larger with bempedoic acid compared with placebo. The submitting company did not present sufficiently robust clinical and economic evidence to gain acceptance by SMC.	07.12.2021
antidolorifico	Daratumumab	In combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who are eligible for autologous stem cell transplant.	Medicine advice	<a href="https://www.cadth.ca/medicines-at/daratumumab">https://www.cadth.ca/medicines-at/daratumumab</a>	daratumumab (Darzalex) is accepted for use within the jurisdiction.	The addition of daratumumab to bortezomib, thalidomide and dexamethasone was associated with a significant improvement in overall response rates in patients with newly diagnosed multiple myeloma who were eligible for autologous stem cell transplant. This advice applies only in the context of an approved Medication Review Access Scheme (MRAS) arrangement following the cost-effectiveness results upon which the decision was based, or a HAQ for price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PAC) meeting.	18.02.2021

**NEWSLETTER: News from the HTA Agencies**  
OCTOBER 2021  
SUMMARY

Agency	Drug Number	Drug Name
CADTH Evidence Based	7	azacitidine, decitabine, cedazuridine, givosiran, incobotulinumtoxinA, <b>liraglutide</b> , risperidone
HAS	10	acide tranexamique, dapagliflozine, ivacafator, méasalazine, <b>nivolumab</b> , nivolumab + ipilimumab, pembrolizumab, stripentol, solution de cardioplegie, tadalafil + ivacafator + (ivacafator)
ICER	3	eculizumab, eftargitimid; mavacamten
IQWiG	13	angiotensin ii acetate, brentuximab vedotin, <b>cabozantinib</b> , elotuzumab, empagliflozin, glecaprevir + pibrentasvir, <b>nivolumab</b> , osimertinib, risdiplam, satralizumab, tralokinumab
NICE	9	apalutamide, atezolizumab, berotralstat, <b>incislar</b> , <b>nivolumab</b> , pembrolizumab, secukinumab, tofacitinib
Scottish Medicines Consortium	11	avapritinib, bempedoic acid + ezetimibe, cabotegravir, <b>cabozantinib</b> , chloroquine, empagliflozin, isatuximab, <b>liraglutide</b> , midazolam, olaparib, vericiguat

Nel mese di riferimento è selezionato il materiale informativo per la formazione della Newsletter, attraverso i siti web delle sei A-HTA.

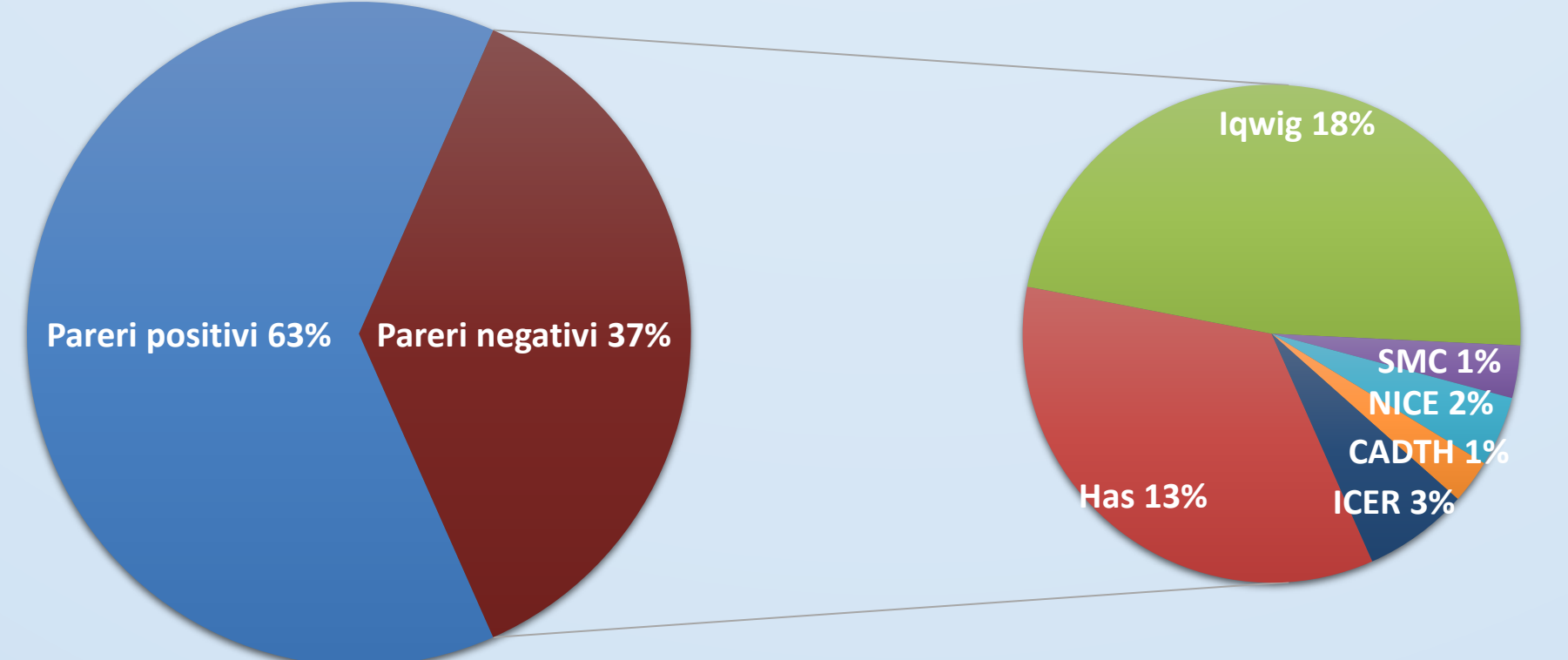
È stato creato un database excel con sei fogli di lavoro (uno per ogni A-HTA), che riporta per ciascun farmaco le seguenti informazioni: denominazione generica e commerciale, indicazione, decisione su rimborsabilità e prezzo, tipo di dossier e link di accesso.

La Newsletter riporta in prima pagina un quadro sinottico dei farmaci valutati dalle A-HTA. Nelle pagine interne sono riportati i farmaci con i relativi dati archiviati nel database.

### Risultati

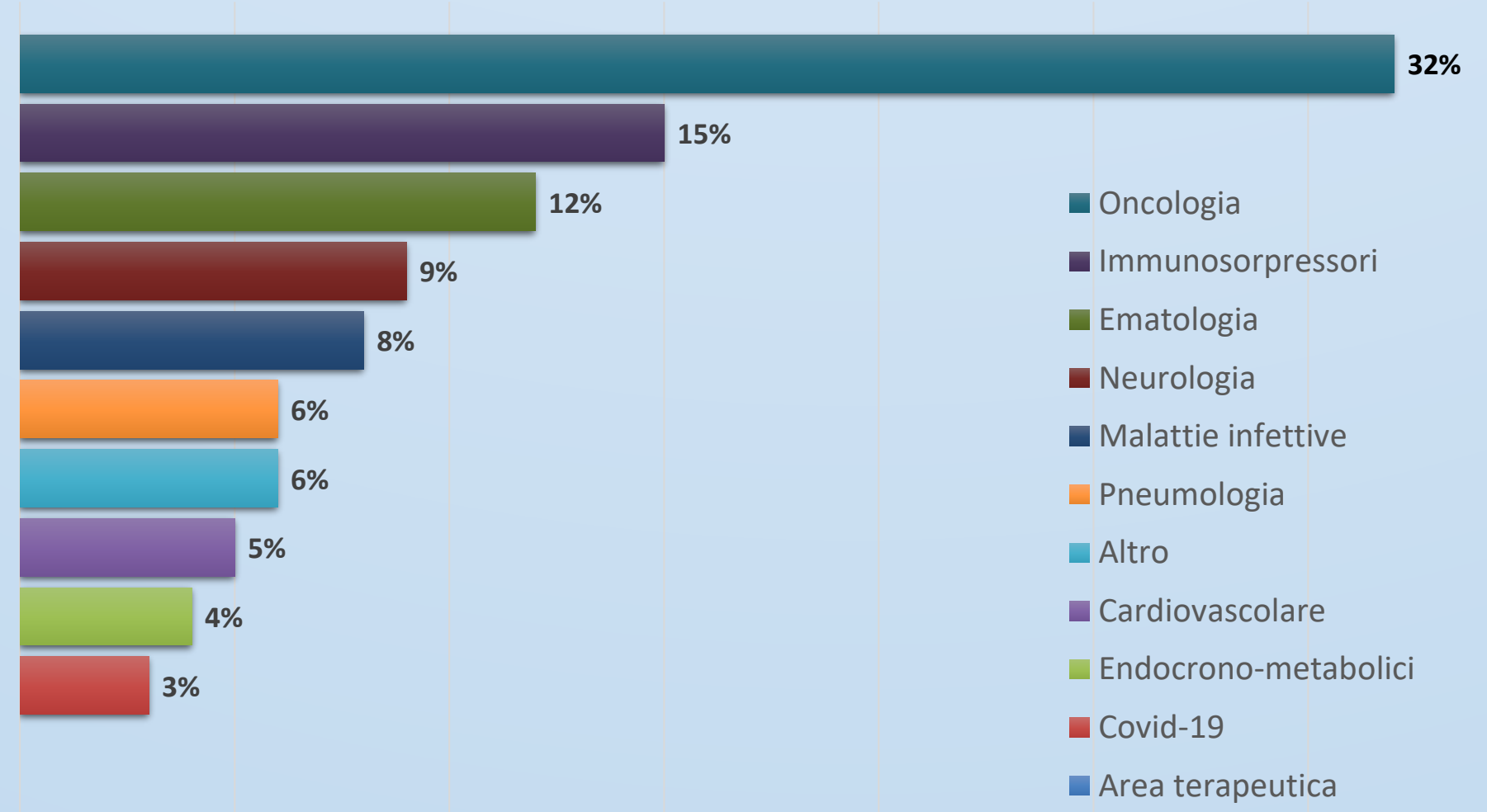
#### Report redatti

Da dicembre 2020 ad agosto 2021 sono state redatte nove Newsletter. Le sei A-HTA hanno prodotto 479 report, di cui il 63% forniva un parere favorevole al rimborso. Il 18% dei pareri negativi è stato emesso da Iqwig.



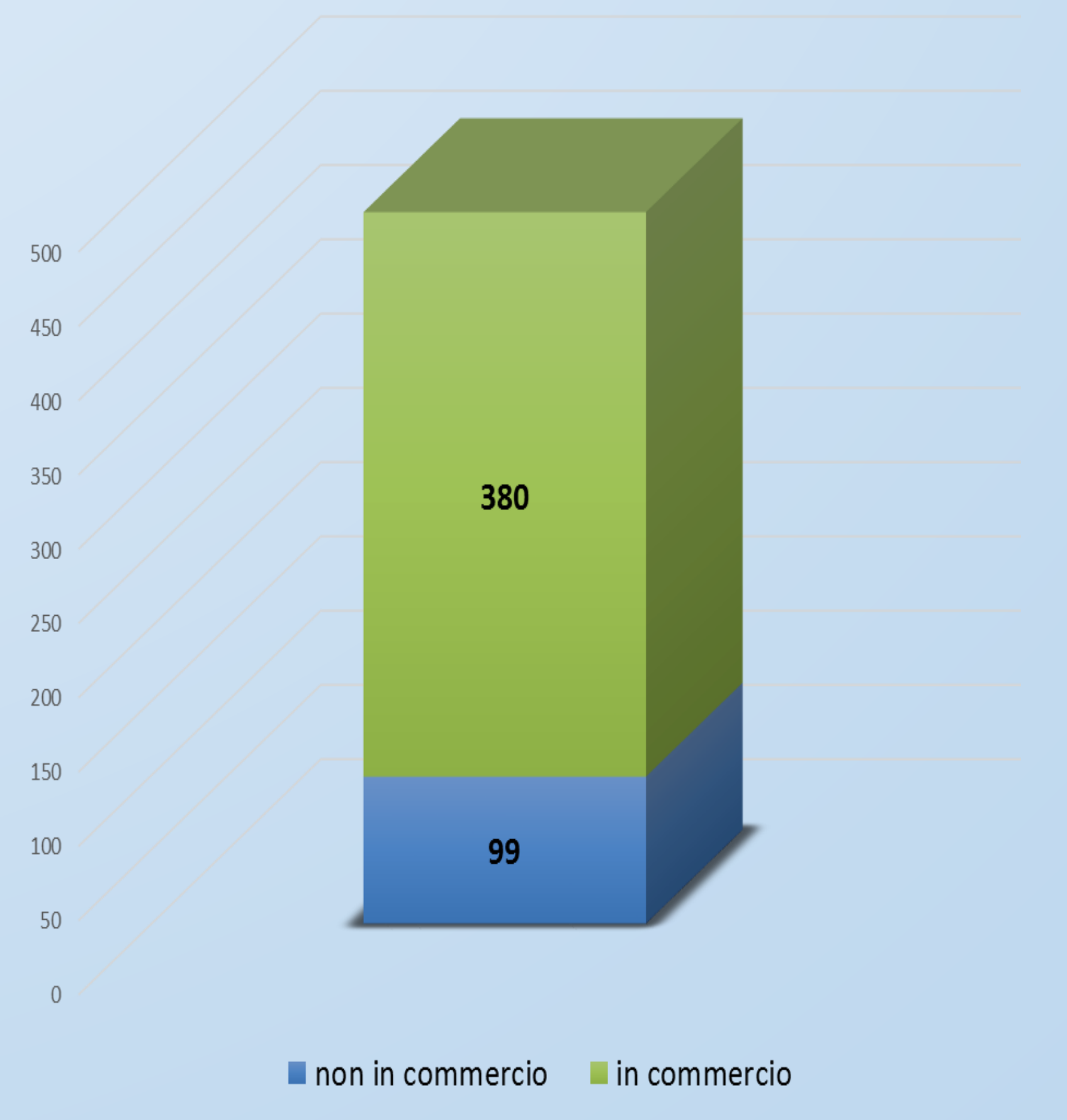
#### Aree terapeutiche

Le principali aree terapeutiche di interesse principali sono risultate essere: oncologia 152/479 (32%), i farmaci immunosoppressori 17/479 (15%), i farmaci dell'area ematologica 56/479 (12%).



#### Farmaci (non) in commercio in Italia

Dei 479 report, 99 (21%) riguardano NCE/NI non presenti in Italia al 15/09/2021.\*



### Conclusioni

La disponibilità mensile, in un unico strumento, di importanti informazioni relative alle decisioni assunte dalle principali A-HTA sui nuovi farmaci consente ai valutatori/decisori di monitorare regolarmente le novità terapeutiche e di disporre di un utile supporto decisionale.