



Danish Headache Centre



Discrepancy between the recommendations and reimbursement regulations of the anti-CGRPs in the Nordics

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Disclosures

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Recommendations and reimbursement rules for treatment with CGRP-mAbs in the Nordics

- Which patients are eligible for treatment?
- Requirements for treatment
- Regulations
- Reimbursement rules
- How many patients?
- What to do to improve the situation for our patients?
- Thanks to Marja-Liisa and Mikko Kallela (Finland), Ingela Nilsson Remahl (Sweden), Lars Jacob Stovner (Norway) and Teva representatives for input

Which patients are eligible for treatment?

	Norway	Sweden	Finland	Denmark
Who regulates?	The Norwegian Medicines Agency (Statens legemiddelverk)	TLV (national reimbursement authority) New Treatment (NT) council issues recommendations	Kela (Social Insurance Institution of Finland)	Danish Medicines Agency (Lægemiddelstyrels en) and Medicinrådet (recommendations)
Which patients can receive treatment?	Chronic migraine	Chronic migraine	$8 \ge$ migraine days per month	Chronic migraine
Are previous treatment failures required?	Failure* of preventive drugs from 3 different classes	Failure* of 2 preventive drugs	Failure* of at least 2 preventive drugs	Failure* of at least 1 anti-hypertensive and 1 anti-epileptic drug

* Failure defined as lack of effect or intolerable side-effects

Requirements for treatment

	Norway	Sweden	Finland	Denmark
Has MOH to be treated before starting CGRP-mAbs?	Yes	Not a requirement by TLV for reimbursement, but a recommendation from NT council	No	Yes
Is failure to Botox required?	No	No	No	No
May both CGRP- mAbs and Botox be given?	Yes	This is not specified by neither TLV nor NT	Yes	No
Who can treat	Neurologists working at hospitals or in private practice. Physicians working at public hospitals	Neurologists working at hospitals or in private practice. Pain specialists trained to treat severe headache	Neurologists working at hospitals or in private practice. Physicians being migraine experts	Neurologists working at hospitals (not in private practice)*

* Treatment currently only given in 6 headache clinics in Denmark

Requirements for treatment

	Norway	Sweden	Finland	Denmark
Response needed to continue treatment?	Effect (not specified) after 12 weeks	No requirement for reimbursement (TLV). NT council recommends: At least 30% reduction in migraine days after first 3 months	At least 50% reduction in migraine days at weeks 9-12 after starting the treatment	At least 30% reduction in moderate to severe migraine days or severe headache days
How often has response to be controlled	After first 3 months. Then every year	Not specified by national authorities	According physician's preference	After first 3 and 6 months. Then every 6 months
Has treatment to be paused?	No, but new evaluation and prescription has to be made once a year	No requirement for reimbursement. NT councils recommends: Yes after 12-18 months	No	Yes for 1 month every 18 months

Regulations

	Norway	Sweden	Finland	Denmark
Which CGRP- mAb should be used?	All 3* can be used	All 3* can be used. NT council recommends: In case of price differences the most cost-effective should be used	All 3* can be used	Cheapest* (as a general rule)
Can you switch among CGRP- mAbs?	Yes	Yes	Yes	No: If no response to first drug Yes: If side-effects

* Erenumab, fremanezumab and galcanezumab

Reimbursement rules

	Norway	Sweden	Finland	Denmark
Who pays for the treatment?	Patient pays maximally 250 Euros per year for all reimbursed drugs together. Norwegian state reimburse the rest	Patient pays maximally 240 Euros per year for all reimbursed drugs together. Swedish state reimburse the rest	Patient pays first 580 Euros per year. After this, the Finnish state reimburses almost 100%	Danish state. Everything is free for the patient
Where do the patients get the drug?	From pharmacy. Physicians have to apply for reimbursement before treatment and then every year	From pharmacy	From pharmacy. Physicians have to apply for reimbursement before treatment, at 6 months and then every 2. year	From hospital

How many patients?

	Norway	Sweden	Finland	Denmark
Approximately, how many are currently being treated?	7,500	4,000	4,400	1,300
Approximately, how many are currently on waiting list?	Not known	Not known	There is no waiting list	600 from headache clinics. More patients are waiting to be seen first time at headache clinics

Conclusions.

What to do to improve the situation for our patients?

- Huge differences in number of patients treated between the Nordic countries (five times as many treated in Norway compared with in Denmark although Norway has slightly fewer inhabitants. Twice as many in Finland compared to Sweden per inhabitant)
- Denmark has most strict rules on monitoring of treatment and on who can treat
- More widely available treatment options are needed (more headache clinics and more private physicians should be willing and able to treat)
- Frequent episodic migraine should also have the possibility for treatment (already possible in Finland)
- What else could improve the situation for our patients and how do we obtain this?

Thank you for your attention



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