Optimizing the lanadelumab-flyo Regimen in the Prophylaxis of Hereditary Angioedema

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ABSTRACT

Rationale: Lanadelumab-flyo is indicated to prevent attacks of hereditary angioedema (HAE). Extension of the dosing interval from every two weeks to every four may be considered when a patient is attack-free for more than six months, eight months from start of care when factoring in a 70-day run-in to steady state. A pharmacist can assist prescribers in optimizing the dosing interval in appropriate patients.

Methods: The medical records of patients receiving lanadelumab-flyo were retrospectively reviewed for documentation of pharmacist-prescriber collaboration in furtherance of extending the dosing interval beyond Q2W. Patient data were included in the analysis if four criteria were met: aged 18-89, monthly lanadelumab-flyo dispenses covered consecutive days of service (+/-7 days) over a minimum of eight months, no patient-reported breakthrough attacks, and drug was covered by a payer without data use restrictions.

Results: 69% (54/78) of pharmacist recommendations to extend the dosing interval were declined; 31% (24/78) were accepted. In fourteen accepted cases, patients appealed to continue Q2W dosing. Fear of breakthrough attacks was cited by all, and the majority (64%; 9/14) reported a history of laryngeal swelling significant to compromise their airway. Prescribers deferred in all cases.

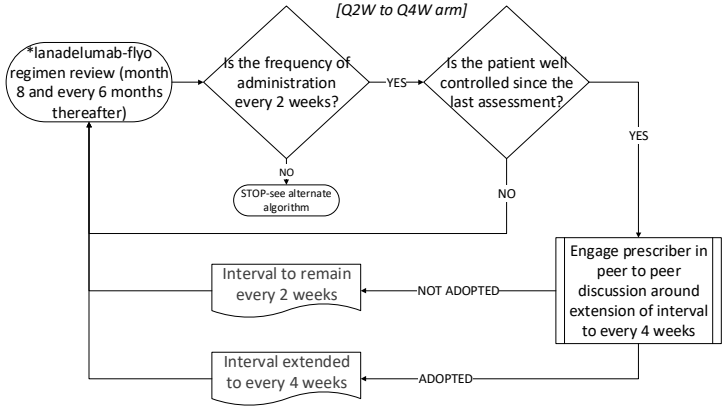
Follow-up data available for the ten patients who successfully converted to an extended dosing interval revealed that eight remained attack free for up to 12 months (range 1-12), while two reported only one and two acute attacks at months five and seven, respectively.

Conclusions: Pharmacist-prescriber collaboration facilitates extended interval dosing in eligible patients receiving lanadelumab-flyo.

METHODS

As part of the specialty pharmacy clinical model, lanadelumab-flyo prophylaxis regimens are proactively assessed by the specialist pharmacist eight months after therapy initiation and every six months thereafter (figure 1). The product labeling supports interval extension from every 2 weeks to every 4 weeks when a patient has been well-controlled (i.e., attack free) for a minimum of six months. The first assessment to this benchmark is scheduled at eight months following the start of care in deference to a published 70-day run-in to steady state. Findings of this review are documented in the patient medical record. On identification of a regimen that is eligible for interval extension per protocol, the prescriber is engaged to discuss adjustments in alignment of evidence-based guidelines and product labeling to patient-level disease presentation. Outcomes from this peer-to-peer discussion are documented in the electronic medical record – including memorialization of clinical rationale when the regimen remains unchanged.

Figure 1: Regimen Optimization Algorithm – lanadelumab-flyo [Q2W to Q4W arm]



Patients were included in the final sample if they were aged 18-89, received monthly lanadelumab-flyo dispenses (at an every 2-week dosing interval) covering consecutive days of service, reported zero attacks during the review period, and the drug was covered by a payer without data use restrictions.

Baseline data collection included: patient age, gender, weight, body mass index, HAE history (age of onset, family history, attack location(s), laryngeal attacks and intubation) and characteristics (HAE type, prodrome, trigger(s)), and annualized attack rate and severity. The medication profile was also reviewed for medications contraindicated in patients with HAE (i.e., ACE inhibitors and DPP-4 inhibitors) and on-demand therapies to treat acute attacks.

RESULTS

A total of 78 regimens met full criteria for inclusion in the final data set. Figures 2, 3, and 4 illustrate distribution of the sample by gender, age, and BMI, respectively.

Figure 2: Gender

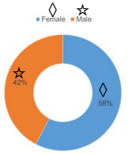


Figure 3: Age

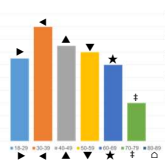


Figure 4: Body mass index

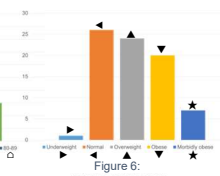
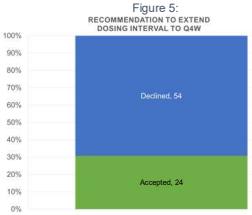
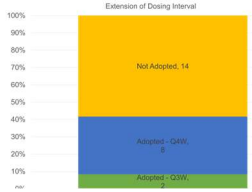


Figure 5:



While 31% (24/78) of specialist pharmacist recommendations to extend the dosing interval were accepted by the prescriber (figure 5), only 42% (10/24) of those were adopted in practice (figure 6).

Figure 6:



All fourteen patients who lobbied their prescribers to remain on every-other-week dosing cited anxiety around and fear of experiencing breakthrough attacks (figure 7). Nine (64%; 9/14) of those patients had a past medical history significant for a laryngeal attack. One patient (7.1%; 1/14), while never experiencing a laryngeal attack personally, lost a sibling to the phenomenon.

Figure 7:

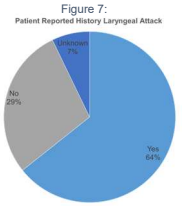
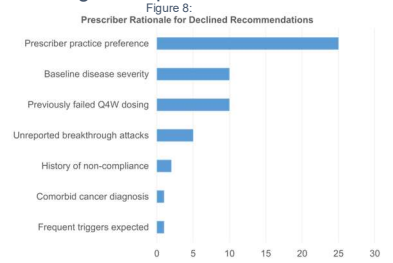
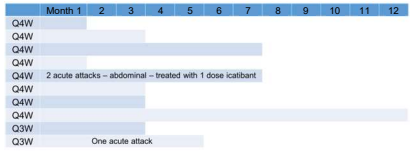


Figure 8:



69% (54/78) of pharmacist recommendations to extend the dosing interval were declined. Figure 8 illustrates specific prescriber rationale for non-adoption of the specialist pharmacist recommendations. The most common reason cited was prescriber practice preference to maintain the dosing interval at every 2 weeks.

Figure 9: Follow-up data



Follow-up data available for the ten patients who successfully converted to an extended dosing interval revealed that eight remained attack-free for up to 12 months (range 1-12), while two reported only one and two acute attacks at months five and seven, respectively. All reported attacks were successfully treated with a single dose of acute use medications.

REFERENCES

1. *Takzyro®* [package insert]. Lexington, MA: Takeda Pharmaceuticals; 2023.

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CONCLUSIONS

Extending a patient's lanadelumab-flyo dosing interval from every two to every four weeks is an important dosing consideration and an important decision for the patient and prescriber. Especially in a disease state where stress can trigger an attack, the ultimate choice should be made collaboratively, assessing both the patient's therapeutic goals and the patient's fears and anxieties. The pharmacist can play a critical role in identifying patients, who may be suitable candidates for a longer dosing interval. When appropriate, regimen optimization can positively impact the patient's quality of life, as well as patient, payer, and system costs.