Norfolk & Waveney ICS Ophthalmology summary

1. Document Control Sheet

Name of document:	Norfolk & Waveney ICS Ophthalmology summary
Description of policy	N&WICB high-cost drug ophthalmology overview for nAMD, DMO, BRVO, CRVO, CNV & non-infectious uveitis
Version	1.0
Scope	
Prepared by	Medicine optimisation team With input/advice from specialists at NNUH, QEH & JPH
Impact Assessment (Equalities and Environmental)	
Other relevant approved documents	
Evidence base / Legislation	Level of Evidence: ~~A. based on national research based evidence and is considered best evidence~~ **B. mix of national and local consensus** ~~C. based on local good practice and consensus in the absence of national research based information.~~
Dissemination	Is there any reason why any part of this document should not be available on the public web site? ~~Yes~~ / **No**
Approved by	N&WICB Therapeutics advisory group
Authorised by	N&WICB Therapeutics advisory group
Review date and by whom	March 2026
Date of issue	06/03/2024 (TBC)

1.1 Revision History

Revision Date	Summary of changes	Author(s)	Version Number
05/09/2022	Condensed all currently agree pathways into one document, simplified nAMD algorithm and updated to match brand guidelines. Although Changes to current commissioning position: • Included 1 switch for C/BRVO (as per NHS England guidelines). • Added Brolicizumab to DMO pathway (TA820) – previously not included due to lack of interest from local specialist team.	A. Charlwood	1.0

1.2 Approvals

This document requires the following approvals either individual(s), group(s) or board.

Name	Title	Date of Issue	Version Number
Norfolk & Waveney ICB Therapeutics Advisory Group		06/03/2024 (TBC)	1.0

Norfolk & Waveney ICS Ophthalmology summary

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Condition	Wet age-related macular degeneration	Diabetic macular oedema	Retinal Vein Occlusion		Choroidal neovascularisation	Non-infectious uveitis
			Branch RVO	Central RVO		
Preferred first line[1]	Ranibizumab (TA155)	Ranibizumab (TA274)	Ranibizumab (TA283) Dexamethasone[$] (TA229)		Ranibizumab (TA298)* Bevacizumab (Local)	Dexamethasone[&] (TA460) Aflibercept[&] (TA460)
Alternative Anti-VEGF[1]	Aflibercept (TA294) Brolucizumab (TA672) Faricimab (TA800)	Aflibercept (TA346) Brolucizumab (TA820) Faricimab (TA799)	Aflibercept (TA409)	Aflibercept (TA305)	Aflibercept (TA486)	Aflibercept (TA486)
Alternative steroid implants[4]		Dexamethasone (TA824)[+] Fluocinolone (TA613) [++]	Dexamethasone[$$] (TA229)			Fluocinolone (TA560)[&&]
Anti-VEGF switches[2]	1^	1	1		0	0
Condition specific notes	^ In addition to switching due to secondary failure, there is another switch commissioned due to primary failure, and another meets high frequency criteria[5]	+ Dexamethasone is commissioned for a maximum of **six doses**, with a minimum 6-monthly interval between doses for DMO. ++ Fluocinolone is only commissioned for use in eyes with a pseudophakic lens	$ Laser not appropriate comment $$ Dexamethasone is commissioned for a maximum of **two doses**, with a minimum 6-monthly interval between doses for RVO.		* CNV secondary to AMD or PM, Ranibizumab should be initiated.	& Preferred first line treatment dependant to criteria as per TA/Local pathway. Please see full algorithm for detail. && If Dexamethasone used as first line intervention, then consider Fluocinolone to prevent relapse.

1. Therapeutic options listed by active drug. If available, interventions with **biosimilar products should be initiated** instead of the originator biologic.
2. Anti-VEGF switches commissioned after **secondary failure** (i.e., treatment failure occurring after initial review period).
    a) In addition, there is a single switch commissioned due to primary failure, and another switch commissioned if high frequency threshold is met[5].
3. Anti-VEGF treatment is preferred first line intervention for all indications. If Anti-VEGF treatment is contraindicated, then steroid implants may be used first line.
4. Switching to an Anti-TNF after steroid implant is **not commissioned.**
5. **Switching criteria**: Consider switching if one of the following apply:

- Primary failure - Where clinical response to the product is insufficient, or where the patient has an intolerable adverse reaction before the initial review period.
- Secondary failure - Where after initial remission, loss of efficacy is experienced after the initiall review period.
- High frequency - Consider switching to a different Anti-VEGF in pathway (where switch is commissioned), if a patient is requiring more than the following doses per year:

Biologic	Year 1 annual injections	Year 2 onwards	Y2 dosing interval
Ranibizumab	8	8	≥7 weeks
Aflibercept	8	8	≥7 weeks
Faricimab	6	4	≥13 weeks
Brolucizumab	7	5	≥11 weeks

Wet AMD

Patient must meet following criteria:

☑ The best-corrected visual acuity is between 6/12 and 6/96
☑ There is no permanent structural damage to the central fovea
☑ The lesion size < 12-disc areas in greatest linear dimension
☑ Recent disease progression (e.g. blood vessel growth, shown by fluorescein angiography, or recent visual acuity changes)

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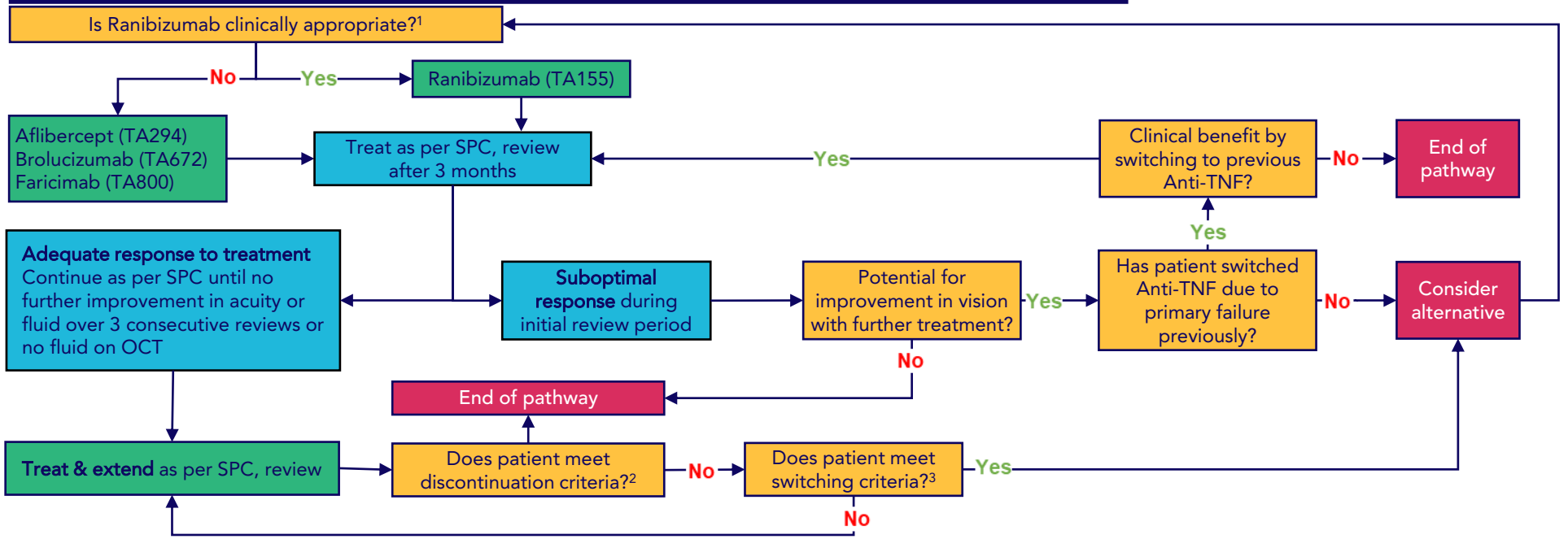

1) If ranibizumab biosimilar is contraindicated or not clinically appropriate for the specific patient or there are specific clinical considerations (subretinal bleed >50% of lesion, idiopathic polypoidal choroidal vasculopathy (PCV)) then, subject to the criteria specified in the relevant NICE technology appraisal guidance, clinicians should consider aflibercept, brolucizumab or faricimab.

2) **Discontinuation criteria:**

- A hypersensitivity reaction is established or suspected
- Reduction of BCVA in the treated eye to less than 15 letters (absolute) on two consecutive visits in the treated eye attributable to AMD in the absence of other pathology
- Reduction in BCVA of 30 letters or more compared with either baseline and/or best recorded level since baseline
- There is evidence of deterioration of the lesion morphology despite optimum treatment.

3) **Switching criteria:** Consider switching if one of the following apply, 1 switch for each of the following scenarios is commissioned per patient:

- Primary failure – Where clinical response to the product is insufficient, or where the patient has an intolerable adverse reaction before the initial review period.
- Secondary failure – Where after initial remission, loss of efficacy is experienced after the initiall review period.
- High frequency - Consider switching to a different Anti-VEGF in pathway (where switch is commissioned), if a patient is requiring more than the following doses per year:

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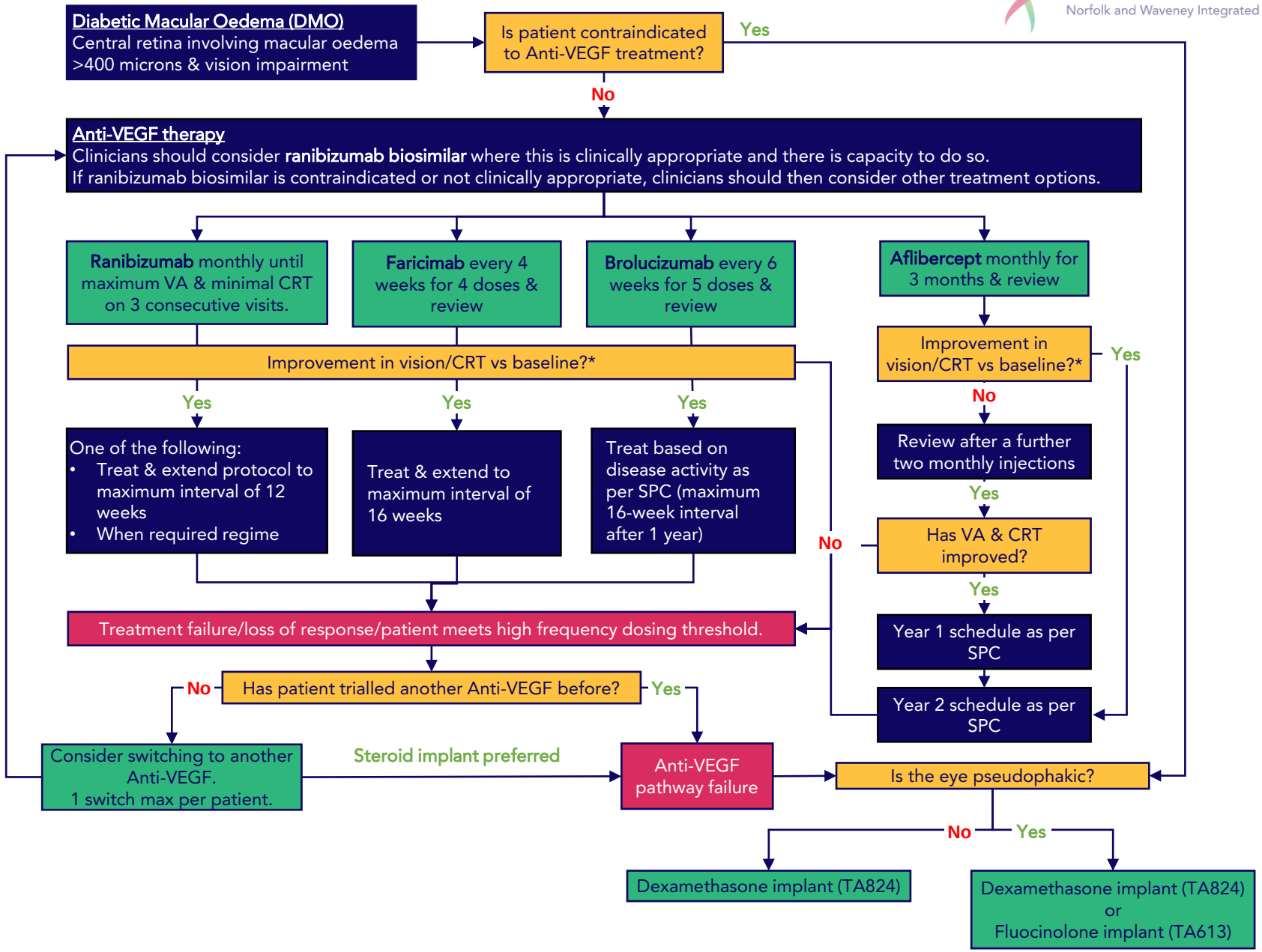

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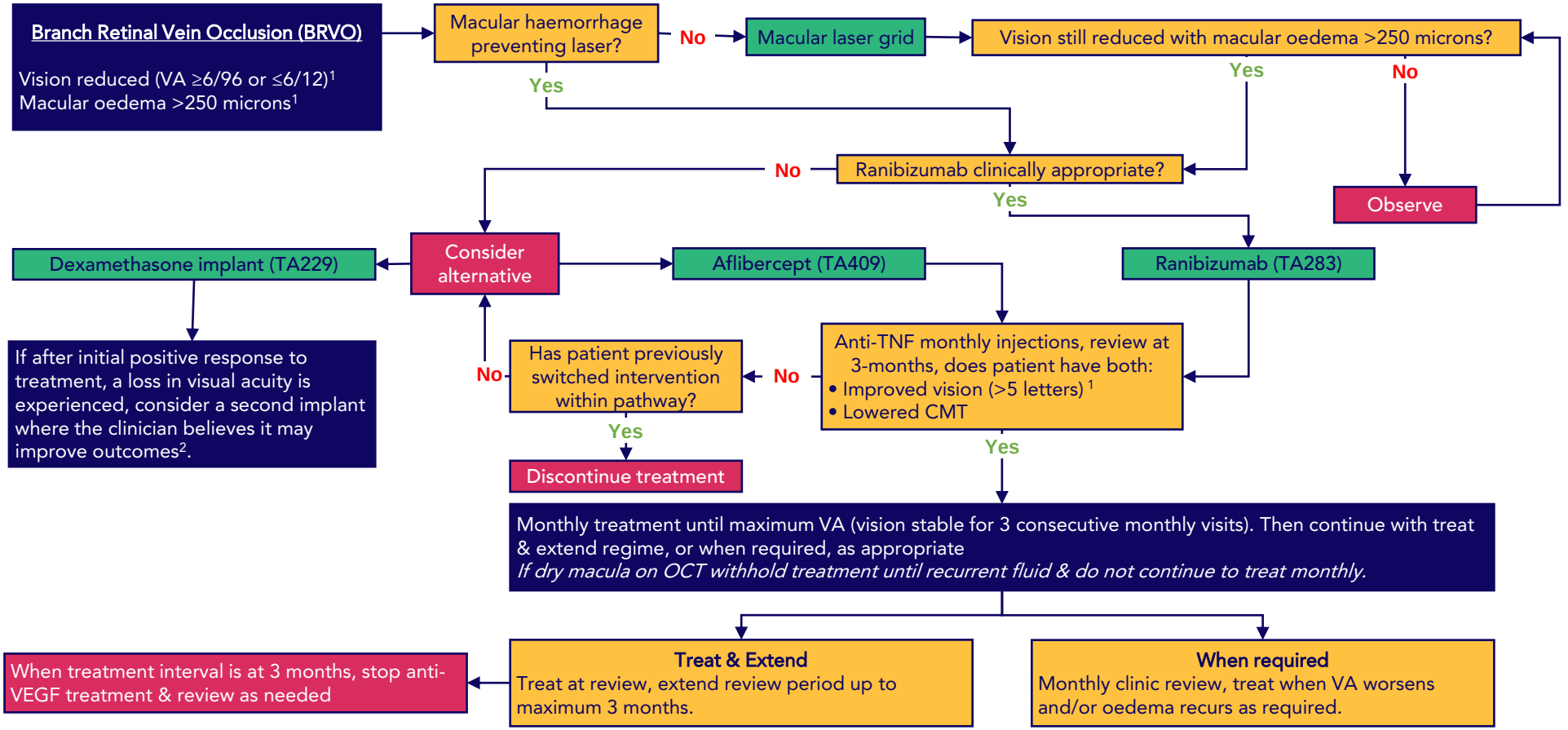

1. Nicholson L, Talks SJ, Amoaku W, Talks K, Sivaprasad S Clinical Guidelines: Retinal Vein Occlusion (RVO). Published online January 2022.
2. Commissioned for a maximum of 2 doses, with a minimum 6-monthly interval.

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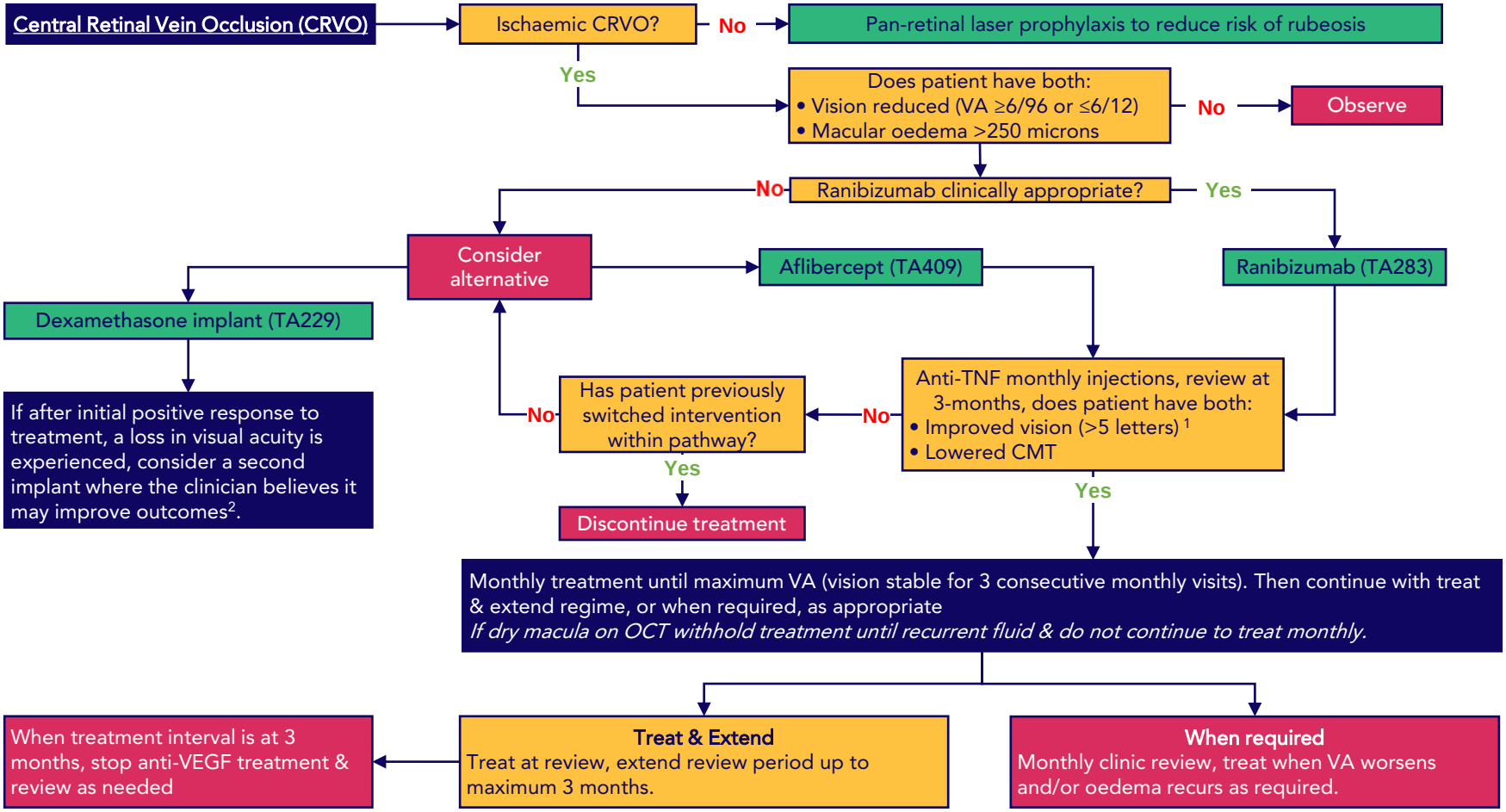

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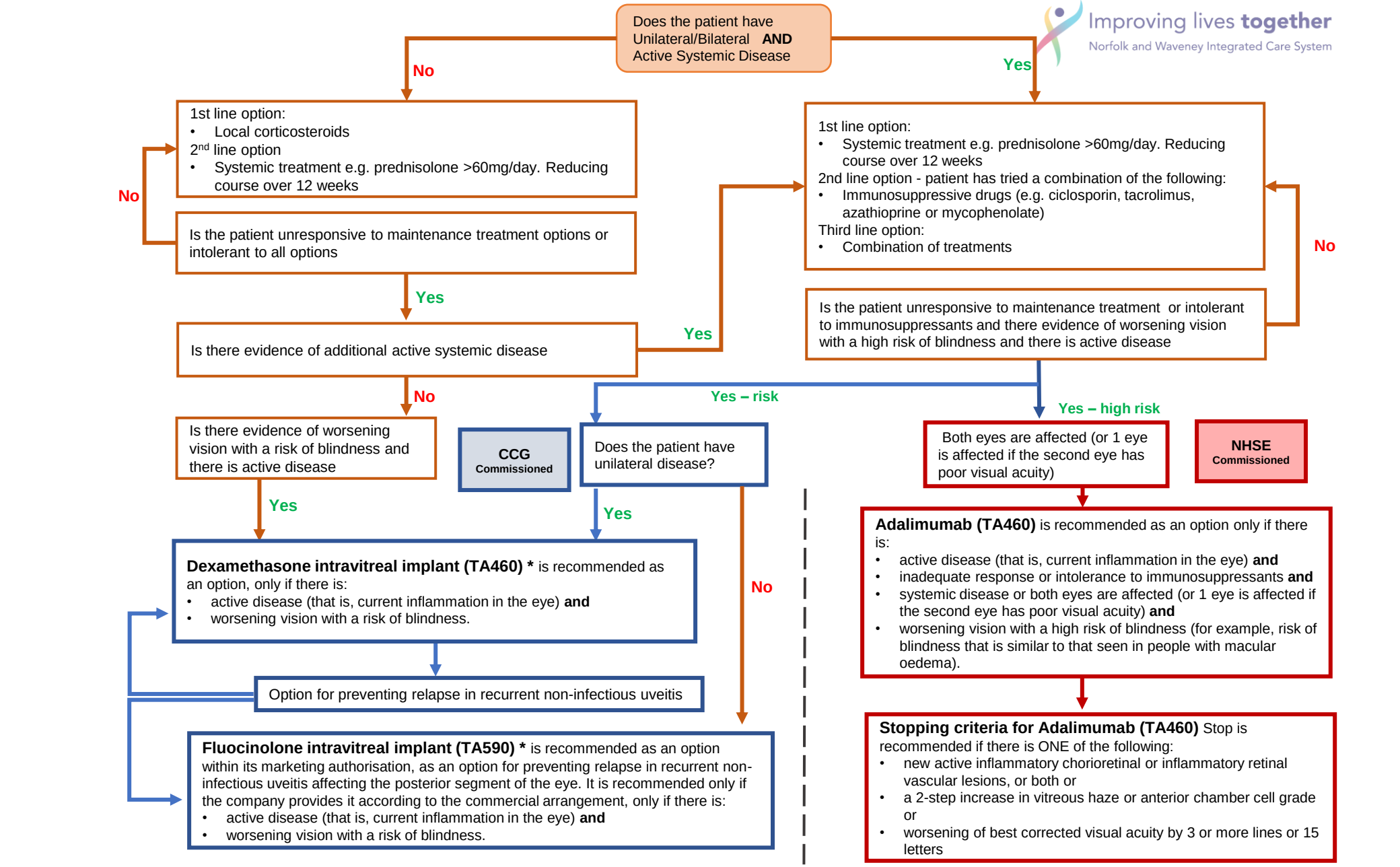
Pathway in support of commissioning guidance for the treatment of non-Infectious posterior uveitis as per TA460 AND including option for treating recurrent non-infectious uveitis affecting the posterior segment of the eye TA590



* Administration to both eyes concurrently is not recommended TA460, TA590/Iluvien SPC