County Durham & Darlington Area Prescribing Committee – Formulary Process

Horizon Scanning & Planning

1.1 Horizon Scanning Document

Annual UKMI Prescribing Outlook document used by RDTC & NECS to create North East Horison Scanning document (expected December)

1.2 FSG Annual Workplan

Horizon Scanning Document submitted to FSG to develop annual work plan.

1.3 Submission to APC

Submit annual workplan to APC (April) for review and comment

1.4 Workplan Notes

The workplan will proactively plan for NICE TAs.

It will also identify when the FSG would recommend a new or updated guideline for NICE TAs and non-NICE products (if an application is submitted).

The guideline may be a simple statement of position in therapy.

Stakeholder Involvement

2.1 Stakeholder Co-ordination

NICE TAs: local workstreams will be reviewed to avoid duplication.

Stakeholders will be identified and contacted regarding implmentation and guideline implications.

2.2 Financial Impact

NICE TAs: Finance and contracting issues will be considered and followed up at this stage.

2.3 Guideline Development

If identified through the workplan or subsequent FSG / APC discussions then the stakeholders will be asked to produce a guideline.

CCG consultation: Guidelines should be sent to each GP prescribing lead who may comment or take to Local Prescribing Group. If required the guideline will go to D&T CAG for consensus.

Application Process

3.1 NICE TAs: no application required

However, where a guideline is required this must be submitted and the stakeholder must identify potential financial impact and contracting implications.

NOTE: If NICE TA is expected within 6m the APC will wait for NICE and not process any applications.

3.2 NICE TAs Summary for APC

A brief summary will be produced at FSG linking NICE TA and submitting the aspects identified above to APC

3.3 Non-NICE / Non-RMOC: await application

Applicant expected to complete full application form and contact other local stakeholders.

3.4 RMOC Products

Applicant expected to complete an abbreviated application form explaining place in local formulary and submit with RMOC review

3.5 Application Review

Application will be reviewed at the FSG. The FSG will identify primary review sources as per TofR. FSG will complete formulary decision aid.

3.6 Individual Organisation Processes

Application/TA will go through processes required by the host organsition (appendix B & C)

APC Decision

4.1 NICE TAs

APC note NICE decision and annotate formulary within 90 days of TA release.

(30 days if Early Access Scheme applies)

This may need a caveat or holding statement as necessary.

4.2 NHS England Decisions

To be noted by the APC

4.3 Non-NICE / Non-RMOC Products

APC will make a decision based on the application, the formulary decision and the primary review source

4.4 RMOC Products

APC will make a decision for inculsion in the local formulary based on the RMOC review and advice

4.4 Online formulary & Cascade

The formulary will be annotated and the decision will be fed back to applicant / stakeholders and cascaded via local organisational processes.

4.6 Appeals Process

Appeals against APC decision making made by applicant to APC Professional secretary - appendix D.

N-TAG appeals - see appendix A

County Durham & Darlington Area Prescribing Committee – Formulary Process

Appendix A: Northern Treatment Advisory Group

N-TAG issue positive recommendation

Review at FSG and invite formulary application from relevant stakeholder(s)

Go to 3.5

N-TAG issue negative recommendation

Review at FSG and annotate formulary with rejected status. Feedback to relevant stakeholder(s)

Follow N-TAG appeals process if appeal noted

Organisation wishes to refer an issue to N-TAG

Review at FSG and agree whether APC or N-TAG is appropriate

Refer to N-TAG or follow APC process from 3.5

Key:

UKMI = United Kingdom Medicines Information Network

RDTC = Regional Drug & Therapeutics Centre

NECS = North East Commissioning Support Unit

FSG = Formulary Steering Group

APC = Area Prescribing Committee

MO = Medicines Optimisation

TA = Technology Appraisal

CCG = Clinical Commissioning Group

N-TAG = Northern Treatment Advisory Group

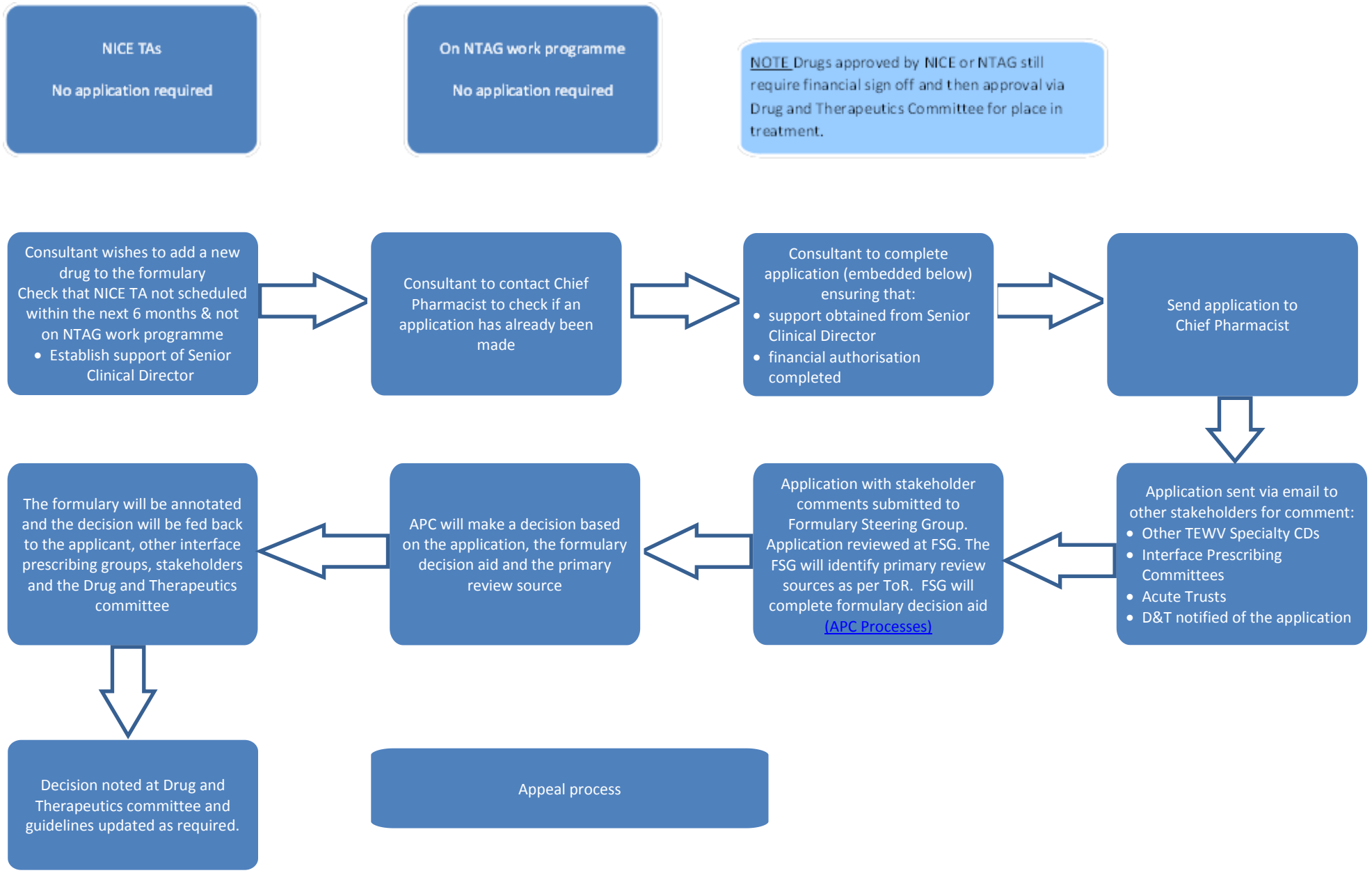
RMOC = Regional Medicines Optimisation Committee

County Durham & Darlington Area Prescribing Committee – Formulary Process

Appendix B: Local Processes for CDDFT and CCGs (link to 3.6)

County Durham & Darlington Area Prescribing Committee – Formulary Process

Appendix C: Tees Esk and Wear Valley NHS Foundation Trust (local process – link to 3.6)



County Durham & Darlington Area Prescribing Committee – Formulary Process

Appendix D: Miscellaneous Processes

Changes to indication

Application for a specific indication

Assessment to be made at APC whether approved indication needs to be stated within formulary.

Subsequent extension to indication

An assessment will be made at FSG regarding impact of change. If impact is expected to be significant or new indication is for a new condition rather than a license extension then an application will be requested.

Go to 3.4

Non-formulary requests from CDDFT and CDD CCGs

Application Completed

To be challenged or authorised by clinical director confirming clinical and financial approval.

Submit to formulary pharmacist

Request for GP to continue?

Submit to designated primary care pharmacist to liaise with GP practice

Approve or reject application and feedback to applicant

Non-formulary request reports

Submit twice yearly report of non-formulary requests to FSG and APC

Aspects included in monthly review of formulary through FSG

Items for automatic inclusion in the formulary:

NICE, N-TAG, MHRA Drug Safety Update

Formulary changes / review need for changes:

Ad-hoc comments received regarding accuracy of individual drugs

Review outside of meeting structure

Hyperlink updates & general house-keeping will be noted on fomrulary updates paper presented at FSG and APC

Review of guideline impact

Review impact of NICE clinical guidelines and key national guidelines on formulary within 3 months of issue

APC appeals process

APC Decision

continued from 4.6

Feedback to applicant

Decision will be notified to applicant within 7 days of APC

Right to appeal

The applicant must notifiy the APC professional secretary within 4 weeks of the decision, if they wish to appeal.

Appeal

This will be heard at next available APC. 20 minutes given for presentation from applicant and questions from APC. Decision will then be communicated to the applicant the following day.