COG Protocol ANBL12P1 FAQs

Central Radiology Review:

We sent the initial pre-treatment and post induction cycle 4 (pre-operative) mIBG scans and reports to QARC for the real-time central review. When will these scans be reviewed?

• One of the objectives of this protocol is to evaluate the feasibility of performing real-time radiology reviews within 21 days of the Post cycle 4 MIBG scan date. Therefore, the scans are reviewed as soon as possible after receipt at QARC. Central review results will not be returned to the institution.

The post cycle 4/pre-op MIBG scan is ready to be sent for the real-time central review. Should I wait for the local Curie scoring to be completed in order to enter our local results to the Institution Curie Score CRF in RAVE and/or submit Appendix I with the scan to QARC for the real-time review?

• No, the post cycle 4/pre-op MIBG scan and report (+/-baseline scan and report if not sent to QARC previously) must be sent to QARC NO LATER than 7 days after scan acquisition. Do not wait for the local Curie score to be completed prior to submitting the real-time central MIBG review materials. You can submit Appendix I to QARC and the Institution Curie Score CRF into RAVE at a later date.

• The Institution Curie Score CRF data should be entered into RAVE for the MIBGs done at diagnosis and Post-Cycle 4 (pre-op) as soon as possible, but this data submission is not be tested in "real-time" in this protocol. A copy of Appendix I for the MIBGs done at diagnosis and Post-Cycle 4 (pre-surgery) can be faxed or emailed to QARC at 401-753-7601 or COG@QARC.org when available. QARC does not forward a copy of Appendix I to COG, so a CRA should keep the original of Appendix I and must still enter the Institution Curie Score CRF into RAVE.

My patient had a gross total resection prior to study entry, so no further surgery is planned. What needs to be submitted for real-time imaging review?

• We will still need the baseline and Post cycle 4 MIBG scans with reports for the real-time review.

My patient's surgery will be delayed until after cycle 5. What needs to be submitted for real-time imaging review?

• We will still need the baseline and Post cycle 4 MIBG scans with reports for the real-time review. If the MIBG scan post cycle 4 is not acquired, we will use the post cycle 5 scan for the review.

How does the real-time central mIBG scan review impact my patient's treatment? It seems like this is already answered above so I took the first sentence out.

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• The central review **is not** used to make treatment decisions and an institution should not wait for review results to treat the patient. ***Review results will not be returned to the institution. All treatment decisions should be based on the institutional assessments.***

Can QARC centrally review the CT/MRI scans or PET scans and provide feedback to help determine patient's disease status at study entry and/or for response/extent of resection?

• Courtesy reviews of the CT/MRI scans and/or PET scans cannot be accommodated.

Radiation Therapy Review:

Does my patient require a boost after 2160 cGy?
• **The patients that require a boost are those that have** residual disease at the primary tumor site >1cm at the ***completion of induction*** and surgery. If they meet this criterion, a boost should be given to the residual disease. The boost dose is an additional 1440 cGy to a total dose of 3600 cGy.

• The presence of gross residual at the primary site of disease at the **end of induction and surgery** is determined by the patient's treating physician in conjunction with other institutional physicians (surgeons and radiologists). This information should be communicated to the treating radiation oncologist.

• The post BuMel consolidative chemotherapy/pre-radiation scans ***ARE NOT*** used to determine if a boost is required.

Is a single phase plan to 3600 cGy allowed?

• A single phase plan to 3600 cGy would only be allowed if the patient had no response to induction chemo and no surgical resection.

Our patient had a gross total resection of the primary tumor done prior to study entry. What volume do we treat?

• If the primary tumor was grossly resected at diagnosis, GTV1 will be based on the initial diagnostic tumor volume (Pre-Op scans).

My patient wants to get proton therapy, is that allowed on ANBL12P1?

• Yes, ANBL12P1 does allow proton therapy. Please refer to section 17.0 of the protocol for details about specific guidelines about proton site credentialing and using proton therapy for the study.

• Please note that IMRT or proton therapy ***is not permitted*** for patients with thoracic tumors when any of the treatment beams transverse normal lung parenchyma.

The treating RT Department sent the RT plan for on-treatment review, when will the case be reviewed.

• There is no on-treatment review requirement for this study. ANBL12P1 has a post RT review only. Protocol required materials should be submitted to QARC within 1 week after the completion of radiation therapy. Please refer to section 17.10 for details about the RT data and diagnostic imaging submission requirements.