No.T-11020/85/2006-NACO/ART
Government of India
Ministry of Health and Family Welfare
National AIDS Control Organisation

9th Floor, Chandralok Building,
36 Janpath, New Delhi – 11001.
Dated: 26th May, 2016

Office Memorandum

Subject: Guidelines for provision of third line ART under National AIDS Control Programme.

In reference to above subject, it has been decided to provide third line ART under National AIDS Control Programme phase IV. The step wise guidance for screening, referral, initiation and follow up of patients failing on second line ART is as below:

In current scenario (where only targeted VL testing is available),

1. All PLHIV on second line should undergo VL testing after 6 months of second line ART.
2. If Plasma Viral Load (PVL) is <1000 copies, second line ART should be continued and follow up monitoring will be done by 6 monthly CD4 count.
3. If PVL is >1000 copies or latest CD4* is
   - Below pre second line treatment value, or
   - Below 50% of peak on second line treatment value, or
   - Below 100 for two consecutive tests at least 6 months apart

   Failure to second line should be suspected.

   **When the routine Viral Load testing is scaled up to ART Centre level, these guidelines will be revised and the treatment failures will then be based on VL tests only.*
4. All cases with suspected second line failure need to be thoroughly evaluated for adherence and any major OI. If adherence is good and there is no major OI, such suspected cases should be referred to Centres of Excellence electronically first with referral form, containing latest relevant reports and complete past history.
5. If adherence is poor or major OI is identified utmost steps need to be taken to improve adherence or treat OI. Such cases shall be closely monitored clinically, immunologically and Virologically (as per availability). If no improvement is seen by 6 months, case should be referred to CoE for further assessment.
6. CoE will give two appointments for these cases and referring centre will confirm one after consultation with patient.
7. Patient will visit CoE as per given appointment. SACEP will thoroughly examine the patient for issues like clinical signs-symptoms, investigations, adherence, OI treatment & prophylaxis.
8. SACEP will refer patient for VL (if not available already). The VL report will be reviewed by SACEP (in absentia) and eligibility for third line will be determined. If PVL is between 1000 and 10,000 copies, CoE shall repeat VL after one month to confirm failure and exclude the possible blips. PLHIV found eligible for third line ART will be given appointment.
9. Third line will be initiated at CoE only by the nodal officer himself / herself under his / her signature and stamp. The preferred regimen for adults is Raltegravir (400 mg) + Darunavir (600 mg) + Ritonavir (100 mg); one tablet each twice daily.

10. The patient will continue third line ART from CoE for at-least 3 months. Once the patient is stable and adherence is >95%, patient can be referred back to nearest CoE / ART Plus centre.
11. Patients on third line shall be monitored by Viral Load Test every 6 months after initiation of third line.
12. Expert opinion of NACEP (nacep.naco@gmail.com) may be obtained in following scenario
    - complicated case
    - patients referred from private
    - multi NRTI exposed cases
    - any intolerance to third line drugs
    - cases requiring these drugs as alternate to second line
    - Any other, as required by SACEP

- Role of SACS and RC: Supply Chain Management for third line will be managed by CoE presently for initial period and later on this will be the responsibility of SACS, instruction regarding same will be sent as and when required. SACS representative will also participate in SACEP (as per existing guidelines) to address administrative issues.
- Follow up Protocol: Detailed follow up protocol and possible side effects / ADRs for third line drug is provided in annexure-1
- Reporting tools: Detailed instructions for reporting tools are being provided in annexure-2. All CoE/ART plus should ensure that they adhere to the instructions and complete various records and reports.
- Once the decision of starting third line ART has been taken by CoE, patient will be transferred out to concerned CoE and then subsequently to concerned ART Plus, after 3months of stipulated treatment.
- Patient-wise details of all patients initiated on third line should be sent to NACO at nacep.naco@gmail.com every month.

Thanks

Dr R S Gupta
Dy Director General (CST) 26/04/2016

To:
The Project Director, All State AIDS Control Societies

Copy to:
Programme Directors of CoE/ pCoE
Nodal Officer, All ART Centres
JD (CST) / Officer In Charge (CST), All SACS
All Regional Coordinators

Copy for information to:
PPS to AS, NACO