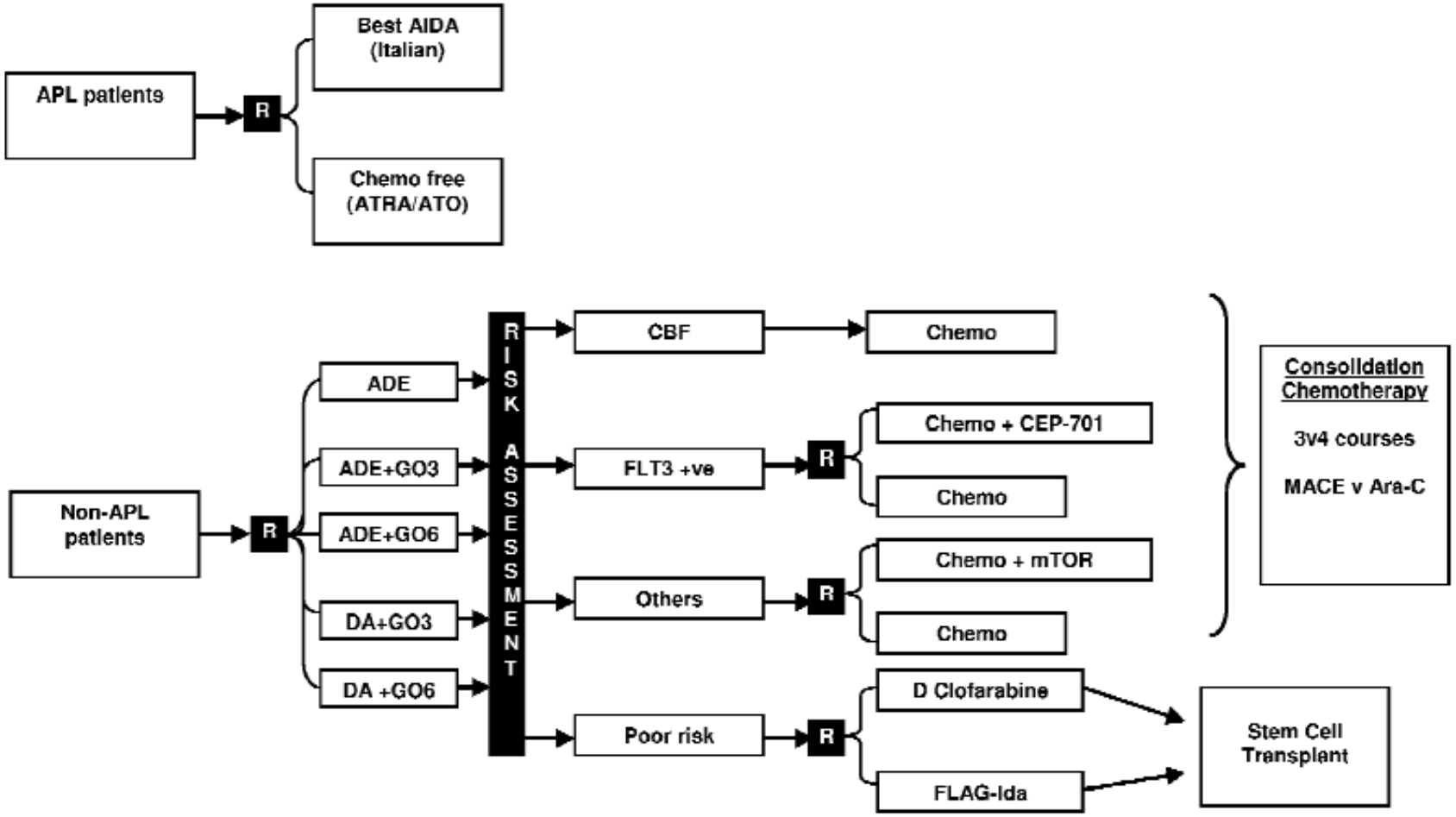
Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.

AML - TRIALS

It is best practise for all patients to be treated on the appropriate NCRI national trial for AML.
It is outside of the remit for this regimen list to provide a comprehensive detail of the regimens in these complex protocols – **PLEASE REFER TO the latest version of the national trial protocol for detailed protocols.**

AML 17 TRIAL = for patients up to age of 60, or if older deemed fit for intensive chemotherapy. AML or high risk MDS (>10% blasts)

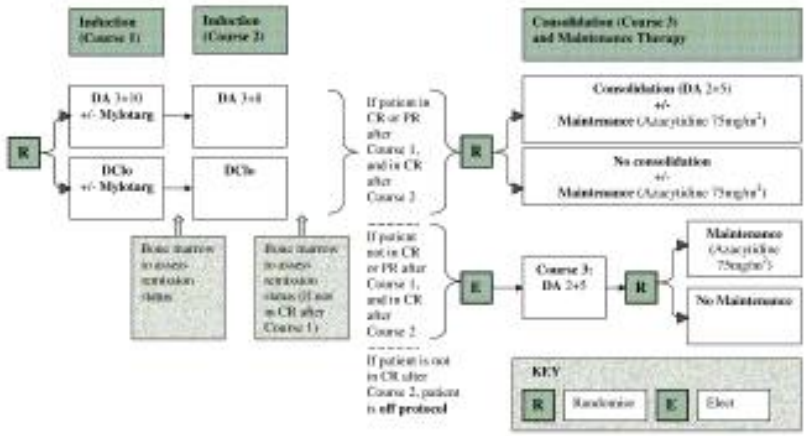
Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.



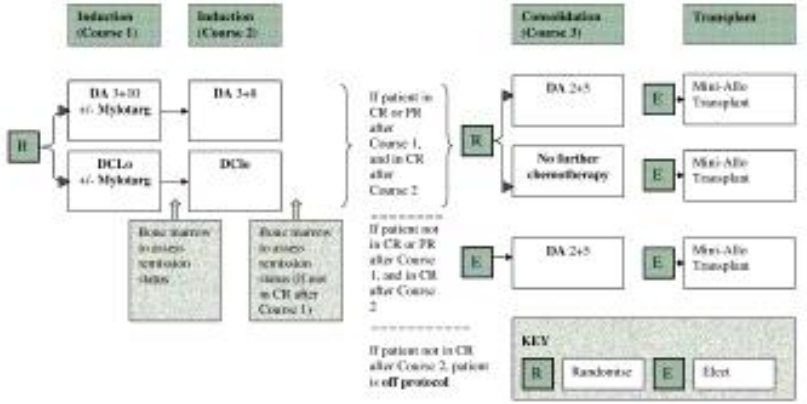
Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.

AML 16 TRIAL = for older patients (age>60) with AML and high risk MDS (>10% blasts).

Flow Chart 1: Intensive treatment for patients *not* scheduled for mini-allo transplant



Flow Chart 2: Intensive treatment for patients scheduled for mini-allo transplant



Flow Chart 3: Non-intensive treatment

Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.

Acute Myeloid Leukaemia – intensive treatment protocols		
REGIMEN	**Indication**	**Drugs**
ADE 10+3+5	Induction chemotherapy (first cycle) for de novo and secondary acute myeloid leukaemia (AML). Usually for patients aged <60 or deemed fit for intensive therapy.	**ADE 10+3+5** Cytosine Arabinoside 100 mg/m^2 12-hourly by i.v. push on days 1-10 inclusive (20 doses). Daunorubicin 50 mg/m^2 daily by slow (1 hour) i.v. infusion on days 1, 3 and 5 (3 doses). Etoposide 100 mg/m^2 daily by 1 hour i.v. infusion on days 1-5 inclusive (5 doses).
ADE 8+3+5	Induction chemotherapy (second cycle) for de novo and secondary acute myeloid leukaemia (AML). Usually for patients aged <60 or deemed fit for intensive therapy.	**ADE 8+3+5** Cytosine Arabinoside 100 mg/m^2 12-hourly by i.v. push on days 1-8 inclusive (16 doses). Daunorubicin 50 mg/m^2 daily by slow (1 hour) i.v. infusion on days 1, 3 and 5 (3 doses). Etoposide 100 mg/m^2 daily by 1 hour i.v. infusion on days 1-5 inclusive (5 doses).
DA 3+10	Induction chemotherapy (first cycle) for de novo and secondary acute myeloid leukaemia (AML). Usually for patients aged	**DA 3+10** Daunorubicin 50 mg/m^2 daily by slow (1 hour) i.v. infusion on days 1, 3 and 5 (3 doses). Cytosine Arabinoside 100 mg/m^2 12-hourly by i.v. push on days 1-10 inclusive (20 doses).

Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.

	<60 or deemed fit for intensive therapy.	

Acute Myeloid Leukaemia – intensive treatment protocols		
REGIMEN	**Indication**	**Drugs**
DA 3+8	Induction chemotherapy (second cycle) for de novo and secondary acute myeloid leukaemia (AML). Usually for patients aged <60 or deemed fit for intensive therapy.	**DA 3+8** Daunorubicin 50 mg/m^2 daily by slow (1 hour) i.v. infusion on days 1, 3 and 5 (3 doses). Cytosine Arabinoside 100 mg/m^2 12-hourly by i.v. push on days 1-8 inclusive (16 doses).
FLAG-Ida	Induction chemotherapy for de novo or secondary AML, with high risk features. For patients <60 or deemed fit for intensive therapy. May be used as salvage regimen for patients with relapsed/refractory disease	**FLAG-Ida:** Fludarabine 30 mg/m^2 daily by 30-minute i.v infusion on days 2-6 inclusive (5 doses). Cytosine Arabinoside 2 g/m^2 daily over 4 hours starting 4 hours after Fludarabine on days 2-6 inclusive (5 doses). G-CSF [Lenograstim 263µg (1 vial)] s.c. daily days 1-7 inclusive (7 doses). Idarubicin 8 mg/m^2 i.v. daily on days 4, 5 and 6 (3 doses).

Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.

REGIMEN	Indication	Drugs
FLAG	Induction chemotherapy for de novo or secondary AML, with high risk features. For patients <60 or deemed fit for intensive therapy. May be used as salvage regimen for patients with relapsed/refractory disease	**FLAG** Fludarabine 30 mg/m^2 daily by 30-minute i.v infusion on days 2-6 inclusive (5 doses). Cytosine Arabinoside 2 g/m^2 daily over 4 hours starting 4 hours after Fludarabine on days 2-6 inclusive (5 doses). G-CSF [Lenograstim 263µg (1 vial)] s.c. daily days 1-7 inclusive (7 doses).
MACE	Consolidation treatment of AML, de novo or secondary disease, usually as third cycle of treatment	**MACE** Amsacrine 100 mg/m^2 daily by 1 hour i.v. infusion (in 5% dextrose) on days 1-5 inclusive (5 doses). Cytosine Arabinoside 200 mg/m^2 daily by continuous i.v. infusion on days 1-5 inclusive. Etoposide 100 mg/m^2 daily by 1 hour i.v. infusion on days 1-5 inclusive (5 doses).
MidAC	Consolidation treatment of AML, de novo or secondary disease, usually as fourth cycle of treatment	**MidAC** Mitoxantrone 10 mg/m^2 daily by slow (1 hour) i.v. infusion on days 1-5 inclusive (5 doses). Cytosine Arabinoside 1.0 g/m^2 12-hourly by 2-hour i.v. infusion on days 1-3 inclusive (6 doses).

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REGIMEN	Indication	Drugs
DClo AML 16	As part of therapy in AML16 trial Course 1 & course 2	Course 1 **DClo** Daunorubicin 50 mg/m² daily by i.v. infusion on days 1, 3 and 5 (3 doses). Clofarabine 20 mg/m² by i.v. infusion over 1 hour daily on days 1 – 5 inclusive (5 doses over 5 days)
DA 2+5 AML 16	As part of therapy in AML 16 trial Course 3	**DA 2+5** Daunorubicin 50 mg/m² daily by i.v. infusion on days 1 and 3 (2 doses). Cytosine Arabinoside 100 mg/m² 12-hourly by i.v. push on days 1 – 5 inclusive (10 doses).
Low dose AraC AML 16 Non-intensive arm	For patients deemed not fit for intensive therapy, as assessed by age and comorbid conditions and frailty index.	**Ara-C 20 mg bd by subcutaneous injection daily on days 1-10 (20 doses) to be repeated at 28 to 42 day intervals**. In some patients it may be necessary to extend the intervals to up to 42 days. A minimum of **4 courses** should be administered. If it is considered appropriate, further courses can be administered (with no limit to the number given). It is intended that low-dose Ara-C will be given in the community although the patient may need to attend as a day case to receive the first dose.

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Low dose AraC + Mylotarg AML 16 Non-intensive arm TRIAL ONLY	For patients deemed not fit for intensive therapy, as assessed by age and comorbid conditions and frailty index. AML 16 trial treatment only	**Ara-C 20 mg bd by subcutaneous injection daily on days 1-10 (20 doses)** ***and*** **Mylotarg (Gemtuzumab Ozogamicin) 5 mg intravenously on *day 1* of Low Dose Ara-C treatment** The treatment should be repeated at **28 to 42 day intervals for four courses**.
Low dose Clofarabine AML 16 Non-intensive arm TRIAL ONLY	For patients deemed not fit for intensive therapy, as assessed by age and comorbid conditions and frailty index. AML 16 trial treatment only	**Clofarabine 20 mg/m² by IV infusion over 1 hour, daily on days 1 to 5** The treatment should be repeated at **28 to 42 day intervals for 4 courses**.
Low dose AraC _ Arsenic trioxide AML 16 non-intensive TRIAL ONLY	For patients deemed not fit for intensive therapy, as assessed by age and comorbid conditions and frailty index. AML 16 trial treatment only	**Ara-C 20 mg bd by subcutaneous injection daily on days 1-10 (20 doses)** **Arsenic Trioxide 0.25 mg/kg on days 1 to 5 (5 doses) and on days 9 and 11 (giving 7 doses in total).**

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APML – primary therapy		
REGIMEN	**Indication**	**Drugs**
AIDA Spanish protocol As per AML 17 trial	Induction of acute promyelocytic leukaemia.	**Idarubicin**, 12 mg/m2/d by intravenous infusion on days 2, 4, 6, 8. **ATRA**, 45 mg/m2/d, will be administered orally in two equally divided doses and rounded to the nearest 10 mg increment, given from day 1 until remission, up to a maximum of 60 days.
	Consolidation Course 1 APML only	**Idarubicin**, 5 mg/m^2/d by short (20 minute) intravenous infusion on days 1, 2, 3, 4. **ATRA**, 45 mg/m^2/d, will be administered orally in two equally divided doses and rounded to the nearest 10 mg increment, given from day 1 to day 15.
	Consolidation Course 2 APML only	**Mitoxantrone**, 10 mg/m^2/d as 30 minute intravenous infusion on days 1, 2, 3, 4, and 5. **ATRA**, 45 mg/m^2/d will be administered orally in two equally divided doses and rounded to the nearest 10 mg increment, given from day 1 to day 15.
	Consolidation Course 3 APML only	**Idarubicin**, 12 mg/m^2/d as short (20 minute) intravenous infusion only on day 1. **ATRA**, 45 mg/m^2/d will be administered orally in two equally divided doses and rounded to the nearest 10 mg increment, given from day 1 to day 15.

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APML – primary therapy		
REGIMEN	**Indication**	**Drugs**
APML maintenance **As per AML 15 trial For Spanish protocol only**	Only for patients with acute promyelocytic leukaemia treated in AML 15 trial.	Maintenance therapy **is only given with the Spanish treatment** and should commence following full haemopoietic recovery from Course 4 (neutrophils > 1.5 x 10^9/l and platelets > 100 x 10^9/l), but not less than 1 month after Course 4. Marrow reassessment for molecular assessment is essential. If RT-PCR is positive, the patient is eligible for treatment as a high-risk patient (see Section 17.11). • **6-Mercaptopurine** (6-MP), 50 mg/m^2/day orally. The dose will be adjusted according to toxicity during the follow-up period. The treatment must be continued for two years. • **Methotrexate** (MTX), 15 mg/m^2 weekly intramuscularly, starting one month after recovery from the last consolidation. The dose will be adjusted according to toxicity during the follow-up period. This weekly treatment must be continued for two years. • **ATRA**, 45 mg/m^2/day orally, for 15 days every three months for 2 years. The first ATRA maintenance course will begin four months after recovery from the last consolidation course. During the days of ATRA administration, the treatment with MTX and 6-MP will be discontinued.

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APML – primary therapy		
REGIMEN	**Indication**	**Drugs**
AML 17 TRIAL ONLY ATRA + Arsenic Induction	Only for patients with acute promyelocytic leukaemia treated in AML 17 trial and randomised to this treatment option.	**All-transretinoic acid (ATRA)**, 45 mg/m²/day will be administered orally in two equally divided doses and rounded to the nearest 10 mg increment, starting on day 1. ATRA treatment will be continued until haematological complete remission (CR, see below for definition) or for a maximum of 60 days. **Arsenic Trioxide** (**As_2O_3=ATO**), 0.30 mg/kg IV over 2 hours daily for 5 days (days 1-5) in week 1, and thereafter 0.25mg/kg IV over 2 hours twice a week for an additional seven weeks. If haematologic CR is not achieved by 60 days after start of induction, patient will go off-study.
AML 17 TRIAL ONLY ATRA + Arsenic Induction	Only for patients with acute promyelocytic leukaemia treated in AML 17 trial and randomised to this treatment option.	**ATRA**, 45 mg/m²/day will be administered orally in two equally divided doses and rounded to the nearest 10 mg increment. Treatment will be administered for 2 weeks on followed by 2 weeks off, for a total of 7 cycles (last cycle administered on weeks 25 - 26). **ATO**, 0.30 mg/kg IV over 2 hours daily for 5 days, in week 1. In weeks two to four ATO will be given on 2 days a week in a dose of 0.25mg/kg. This is followed by four weeks with no treatment. This will be repeated for a total of 4 cycles (last cycle administered on weeks 25 - 28).

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AML – salvage therapy		
REGIMEN	**Indication**	**Drugs**
Salvage regimens for AML frequently incorporate high dose Ara-C. Options include FLAG, FLAG-Ida (see above) and Ara-C/Amsacrine (see below).		
High dose AraC+ Amsacrine	Relapsed/refractory ALL For patients eligible for intensive therapy, who have relapsed or failed to achieve CR after 2 cycles of induction.	**Amsacrine** 200mg/m^2 iv Days 1-3 inclusive **Cytosine Arabinoside** 3gm/m^2 iv Days 1-5 inclusive